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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/06 — A1

(11) International Publication Number: **WO 00/15147**

(43) International Publication Date: 23 March 2000 (23.03.00)

(21) International Application Number: PCT/US99/20714

(22) International Filing Date: 10 September 1999 (10.09.99)

(30) Priority Data:

60/099,767	10 September 1998 (10.09.98)	US
60/104,397	15 October 1998 (15.10.98)	US
60/147,202	4 August 1999 (04.08.99)	US
60/147,218	4 August 1999 (04.08.99)	US
09/369,048	4 August 1999 (04.08.99)	US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 09/369,048 (CIP)
Filed on 4 August 1999 (04.08.99)

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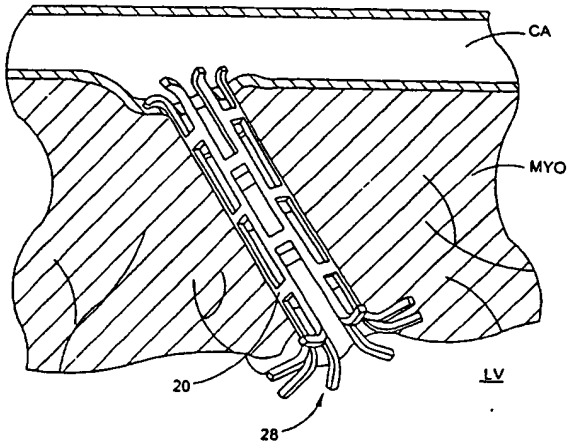
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: TMR SHUNT



(57) Abstract

A conduit is provided to provide a bypass around a blockage in the coronary artery. The conduit is adapted to be positioned in the myocardium or heart wall to provide a passage for blood to flow between a chamber of the heart such as the left ventricle and the coronary artery, distal to the blockage. The stent is self-expanding or uses a balloon to expand the stent in the heart wall. Various attachment means are provided to anchor the stent and prevent its migration. In one embodiment, a conduit is provided having a distal top which is more preferably a ball top, wire top, flare top or flip-down top. These top configurations anchor the shunt at one end in the coronary artery.

TMR SHUNT

Field of the Invention

The present invention relates to an apparatus for bypassing a blocked blood vessel segment, and, more particularly, to a conduit or stent positioned between the coronary artery or other blocked vessel and a chamber of the heart, such as the left ventricle of the heart, to bypass a blocked segment of the coronary artery or other blood vessel.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque, which at the very least impairs the efficiency of the heart's pumping action, and can lead to heart attack and death. In some cases, these arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a bypass of the blocked vessel is necessary.

In a bypass operation, one or more venous segments are inserted between the aorta and the coronary artery. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage, or due to the risk of emboli.

Thus, there is a need for an improved bypass system which is less traumatic to the patient.

Summary of the Invention

Briefly stated, the methods and apparatus described and illustrated herein generally relate to direct coronary revascularization, wherein a conduit or opening is provided from the left ventricle to the coronary artery, oftentimes the left anterior descending (LAD), to provide blood flow directly therethrough. The conduit of the preferred embodiments has a distal top which is more preferably a ball top, wire top, flare top or flip-down top. These top configurations anchor the shunt at one end in the coronary artery.

Brief Description of the Drawings

FIGURE 1A is a cross-sectional view of a human heart, aorta and coronary artery.

FIGURE 1B is a side view of one embodiment of an expandable stent and the balloon catheter used for stent delivery.

FIGURE 2 is a side view of the stent of **FIGURE 1B** mounted on the distal end of the catheter for delivery into the myocardium, with the coronary artery and myocardium shown cut-away.

FIGURE 3 is a side view of the distal end of the stent/catheter assembly of **FIGURE 1B** positioned in the myocardium, with the coronary artery and myocardium shown cut-away.

FIGURE 4 is a cross-sectional side view of the stent of **FIGURE 1B** positioned within the myocardium after removal of the catheter used for delivery.

FIGURE 5 is a side view of another embodiment of the stent and the catheter used for stent delivery.

FIGURE 6 is a cross-sectional side view of the catheter and puncture device used to introduce the self-expanding stent of **FIGURE 5** into the myocardium.

FIGURE 7 is a cross-sectional side view of the stent/catheter assembly of **FIGURE 5** positioned in the myocardium.

FIGURE 8 is a side view of the self-expanding stent of **FIGURE 5** positioned within the myocardium after removal of the catheter and puncture device, with the coronary artery and myocardium shown cut-away.

FIGURE 9 is a perspective view of another embodiment of the stent having expandable legs, showing the stent mounted on the distal end of the introducer catheter.

FIGURE 10 is a perspective view of the stent of **FIGURE 9**, showing the distal end of the introducer catheter pushed forward to allow the legs of the stent to expand.

FIGURE 30 is a schematic, partial cross-sectional view of the self-expanding stent deployed within the myocardium.

FIGURE 31 is a perspective view of another embodiment of a stent having retention members which maintain the position of the stent.

FIGURE 32 is a schematic, cross-sectional view of a human heart, showing a conduit in the myocardium of the heart for forming a bypass shunt between the left ventricle and a coronary artery.

FIGURE 33A is a side view of a wire top shunt according to one embodiment of the present invention.

FIGURE 33B is a side view of a wire top shunt according to another embodiment of the present invention.

FIGURES 33C-33F are schematic side views of wire top shunts inserted into a patient's coronary artery.

FIGURES 33G-33I are schematic side views of a delivery sequence for inserting a wire top shunt.

FIGURE 34A is a side view of a wire top shunt according to another embodiment of the present invention.

FIGURE 34B is a side view of a ball top shunt according to one embodiment of the present invention, the shunt being shown laid out flat.

FIGURE 34C is a side view of the ball top shunt of **FIGURE 34B**, shown implanted in a patient.

FIGURE 34D is a side view of a ball top shunt according to another embodiment of the present invention, the shunt being shown laid out flat.

FIGURE 34E is a side view of a ball top shunt according to another embodiment of the present invention, the shunt being shown in its preassembly configuration.

FIGURE 34F is a side view of a ball top shunt according to another embodiment of the present invention, the shunt being shown laid out flat.

FIGURE 34G is a side view of the ball top shunt of **FIGURE 34F**, shown implanted in a patient.

FIGURE 34H is a side view of a ball top shunt according to another embodiment of the present invention, the shunt being shown laid out flat.

FIGURE 34I is a side view of a ball top shunt according to another embodiment of the present invention, the shunt being shown laid out flat.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. The anatomy of the human heart is illustrated in **FIGURE 1A**. Oxygenated blood flows from the heart PH to the aorta AO, on to the rest of the body, some of the blood flowing into the coronary artery CA. In some individuals, plaque builds up within the coronary artery CA, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death.

In order to restore the flow of oxygenated blood through the coronary artery, one embodiment of the present invention provides for the shunting of blood directly from the heart to a site in the coronary artery that is distal to the blockage. A channel is formed through the wall of the coronary artery and the myocardium and into the left ventricle of the heart that lies beneath the coronary artery. A stent or conduit is positioned in the passage to keep it open, and allow for the flow of oxygenated blood directly from the heart into the coronary artery. Again, it should be understood that while the insertion of the conduit in the myocardium between the left ventricle and the coronary artery is described in detail below, this is merely exemplary and use of the conduit between other chambers of the heart and the coronary artery, and between blood vessels is also contemplated.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial

preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

In some individuals, aortic insufficiency or peripheral venous insufficiency occurs. Aortic insufficiency is the leakage of blood through the aortic valve, resulting in a backflow of blood into the left ventricle. The heart compensates for the backflow of blood by pumping harder, resulting in hypertrophy (thickening of the heart muscle) and dilation of the left ventricle wall. Left untreated, heart failure can result. In venous insufficiency, the heart valves are unable to prevent the backflow of blood. This too can result in heart failure. Accordingly, one embodiment of the invention provides for the use of a conduit placed within the heart wall to improve the flow of oxygenated blood through the body.

Balloon Expanded Stent

A first embodiment of the present invention is illustrated in **FIGURE 1B**. This embodiment is a balloon-expanded stent 10. The stent 10 is introduced as described below, using a high-pressure balloon catheter 12 to deploy the stent 10 once it is properly positioned in the myocardium MYO (**FIGURE 2**). When the stent 10 is positioned inside the myocardial wall MYO, the balloon 14 is inflated to expand the stent 10 and open the conduit from the left ventricle LV into the coronary artery CA. The stent 10 can include attachment mechanisms not limited to hooks, barbs, flanges, large collars, suture holes and/or other means to ensure a seal is created between the coronary artery CA and the wall of the myocardium MYO and to prevent the threat of stent 10 migration. When the attachment of the stent 10 is completed, the remaining catheter assembly 12 is removed, leaving the stent 10 in place. Upon deflating the balloon 14, the stent 10 will remain open. Because of the shape of this stent 10, a dumbbell shaped balloon 14 is preferably used to ensure proper expansion, as described below.

FIGURES 1B through **4** illustrate the introduction of the balloon-expanded stent 10 into the myocardial wall MYO. **FIGURE 1B** illustrates the stent 10 mounted over the balloon 14 on the distal end of the stent introducer catheter 12. **FIGURE 2** illustrates the stent introducer catheter 12 following the path created by a puncture wire 16 extending past the distal end of the introducer catheter 12, and used to access the left ventricle LV through the coronary artery CA and myocardium MYO.

FIGURE 3 illustrates the non-expanded stent 10 positioned inside the myocardial wall MYO prior to inflation of the balloon 14. **FIGURE 4** illustrates an

end to facilitate the placement of these anchoring sutures. A suture gun can be used to apply multiple sutures at the same time. In addition, the stents can be lined, if desired, with materials such as polymers, for example polytetrafluoroethylene (PTFE), silicone or GORTEX, to provide for the ease of blood flow therethrough.

Stent with Attachment Flanges

A third embodiment of the stent design, illustrated in **FIGURES 9-11**, incorporates attachment flanges or "legs" 30 that expand after introduction into the myocardium to hold the stent 34 in place. The puncture instrument 32 and stent 34 are mated together and are advanced into the myocardial wall as a single unit. The puncture instrument's distal end 36 is shaped in a "nose-cone" configuration, which is responsible for containing the legs 30 of the stent 34 while it is being introduced into the wall of the myocardium. When the stent 34 is in the proper position in the myocardial wall, the nose cone 36 is pushed forward, releasing the attachment legs 30 of the stent 34. The internal diameter (ID) of the stent 34 is large enough to allow the nose cone 36 to pass back through. The stent 34 is then released from the catheter 38 and the catheter 38 is removed.

FIGURE 9 illustrates the stent 34 mounted on the introducer catheter 38. The expanding legs 30 of the stent 34 are held in place by the nose cone 36 on the distal end of the catheter 38 that acts as a dilator. The catheter assembly 38 is advanced over a puncture wire if desired, into proper position in the myocardium, and the nose cone 36 is pushed forward allowing the legs 30 to expand as shown in **FIGURE 10**. The nose-cone/puncture assembly 32, 36 is then withdrawn through the lumen of the stent 34. When the nose-cone/puncture assembly 32, 36 is removed, the stent 34 can be pushed off the introducer catheter 38 and remains in the myocardium in the position shown in **FIGURE 11**. **FIGURE 11** also illustrates a sealing collar 44 that may be used in the interface between the coronary artery and the outer wall of the heart to prevent hemorrhaging around the stent 34 and to hold the stent 34 in place. Sutures can be used to ensure that the stent is maintained in its proper position and prevent migration.

Biodegradable Stent

If desired, the stent or conduit of the present invention can be formed of biodegradable or bioabsorbable materials and/or used to deliver drugs directly into the myocardium and the coronary circulation. Such a stent 52 is illustrated in **FIGURE 13**. The biodegradable stent 52 can extend only partially through the myocardium MYO as illustrated in FIGURE 13, but can also extend entirely through

and 19, showing the rings of the bulkhead stent 50 positioned within the myocardium MYO to form the passageway therethrough.

FIGURES 22-25 illustrate more particularly the structure and deployment of the rings comprising the bulkhead stent 50. As shown in **FIGURE 24**, the bulkhead stent comprises a plurality of rings 64 that are initially loaded into the delivery catheter 60. While inside the lumen of the catheter 60, each ring 64 has a loaded configuration 64A, shown in **FIGURES 22** and **25**. After ejectment from the catheter 60, the ring 64 assumes an inserted configuration 64B, shown in **FIGURES 23** and **25**. Preferably, the inserted configuration of ring 64B includes a plurality of flanges 66 around the circumference of each ring 64, thereby providing a securement mechanism to anchor each ring 64 to the myocardium MYO. Each ring 64 transforms from its loaded configuration 64A to its inserted configuration 64B by virtue of being released from the catheter 60. Specifically, the catheter 60 acts as a restraint on each ring 64 to keep it in its loaded configuration 64A. Then, once the ring 64 is released from the catheter 60, the flanges 66 provided along the circumference of each ring 64 are allowed to extend outward to provide the securement mechanism.

FIGURE 26 illustrates an inserter device or handle 68 that may be used in deploying the bulkhead stent 50 into the myocardium. The inserter handle 68 preferably comprises a gun 70 with a trigger 72, and a wire 74 extending from a nozzle 76. The rings 64 (not shown) of the bulkhead stent 50 are preferably loaded onto the wire 74, and may be deployed into the myocardium preferably one at a time by pressing the trigger 72.

Screw Stent

FIGURES 27-30 illustrate another embodiment of the present invention. Here, a self-expanding spring or screw stent 140 is delivered into the myocardium MYO. As illustrated in **FIGURE 27A**, a channel 142 through the wall of the myocardium MYO is first created, as described above, using a device 144 delivered through the aorta AO and coronary artery CA. The channel 142 travels from the coronary artery CA through the myocardium MYO and into the left ventricle LV as shown in **FIGURE 27B**. The distal end of the stent delivery catheter 146 bearing the stent 140 is then positioned within the channel 142, as shown in **FIGURE 28**. Preferably, the position of the distal end of the delivery catheter 146 is checked radiographically, to ensure proper positioning. Next, as illustrated in **FIGURE 29**, the self-expanding spring stent 140 is delivered into the channel 142 wall of the

the unsheathed section of the shunt to the sheathed section. The step between the two tubes also provides a mechanical stop for the shunt which is used to transmit axial force from the sheathed section to the shunt during insertion.

Wire loops 318 are preferably attached to the distal end 314 to form the distal top. The wire loops preferably form a generally ball-shaped configuration, with the diameter of the ball corresponding approximately with the diameter of the artery. When implanted, the wire loops 318 are preferably located in the coronary artery CA to hold the shunt therein. The wire loops 318 preferably expand beyond the diameter of the tubular body. Therefore, these loops are preferably collapsible such that they can be inserted into a delivery tube, as described below.

Although **FIGURE 33A** illustrates a design with two loops, it will be appreciated that multiple designs with different numbers of loops and other configurations are possible. Moreover, loops having different shapes, such as hoops, arches, etc., are also contemplated. Furthermore, wires of different sizes may be used. The wire loops 318 and the tubular body 311 may also be integrally formed from a single piece of material and laser cut into the desired configuration. **FIGURE 33B** illustrates another embodiment having folded down loops 318. In this embodiment the shunt 310 has a proximal end 312 which itself opens into the left ventricle when implanted. The proximal end 312 is pointed to assist in inserting the shunt 310 through the heart wall, as described below.

FIGURES 33C-33F illustrate different embodiments of a loop top shunt implanted in a patient. More particularly, the proximal end (not shown) of the conduit preferably extends into the left ventricle, and the distal end having loops 318 extends into the coronary artery. The loops 318 of each of these embodiments are preferably sized to open against the walls of the coronary artery CA, as shown.

FIGURES 33G-33I illustrate one preferred delivery sequence of a shunt having wire loops 318. It will be appreciated that this delivery method can be applied to other types of shunts, such as the shunts described below. As shown in **FIGURE 33G**, a delivery sheath 326 is placed over the loops 318 to restrain the loops into a collapsed configuration. An optional stylet 327 may also be used to restrain the loops. In this configuration the shunt is implanted into a heart wall, with the loops 318 (located within the sheath 326) being positioned in a coronary artery CA. As shown in **FIGURE 33H**, the sheath 326 is removed, allowing the loops 318 to expand outward. As shown in **FIGURE 33I**, when the sheath 326 is fully

FIGURES 35 and **36** illustrate enlarged views of a shunt 310 with a wire top 322, where the wire top 322 is preferably integrally formed. As can be seen, the wire top 322 preferably uses a four strut design, wherein the tubular body 311 at the distal end 314 transitions into four wires 324 forming the wire top 322. This embodiment is more preferably referred to as a knub top design.

FIGURES 37 and **38** illustrate another embodiment wherein the shunt of **FIGURES 35** and **36** instead have a flat top design.

FIGURES 39A-39F illustrate a preferred deployment sequence of a conduit 310 having a wire top 322. The shunt 310 is preferably inserted into the delivery tube 326, distal end first, such that the wire top 322 is inserted into the tube 326 and is collapsed therein. As shown in **FIGURE 39A**, the delivery tube preferably has a bulged region 328 for receiving the wire top 322 when in its collapsed configuration. The bulged region 328 gives the operator tactile feedback for sensing when the sheath is in the proper position for deployment. The arrangement shown in **FIGURE 39A**, in one embodiment, is inserted into the heart with the proximal end of the shunt 310 extending into the left ventricle and the distal end of the shunt extending into the coronary artery. With the shunt 310 in position, the delivery tube is retracted, as shown in **FIGURES 39B-39F** from the shunt to release the wire top 322 into its expanded configuration in the coronary artery.

FIGURE 40A illustrates another embodiment of a shunt 310 having a flare top 330. The shunt illustrated in **FIGURE 40A** has six flares extending from distal end 314 and integrally formed therewith. It will be appreciated that fewer or more flares may be provided, and that these flares may extend away from the shunt body 311 at various angles to hold the shunt within the coronary artery. These flares are preferably collapsible to allow the shunt to be inserted into a delivery tube such as described above. **FIGURES 40B** and **40C** illustrate a flip-down shunt having sections 332 which fold down when implanted in a patient to anchor the shunt to the artery CA. This shunt 310, as illustrated, has a wire portion 311 and a solid portion 313.

FIGURE 41 illustrates another embodiment of a shunt 310. The shunt 310 has a proximal end 312 and a distal end 314, the proximal end preferably having an opening for receiving blood from the left ventricle. The distal end also has an opening for delivering blood from the left ventricle to the coronary artery. The shunt 310 shown in **FIGURE 41** preferably has a T-flange 376 at the distal end.

Single Loop Conduit

FIGURES 47A and **47B** illustrate an alternative embodiment of a conduit 500, having a single loop 502 (similar to a basket handle) used to anchor the conduit 500 in the coronary artery CA. The conduit 500 is preferably a one-piece construction formed from a nitinol tube. The loop 502 can be heat formed, such that it conforms to the inner wall of the coronary artery CA. The loop 502 includes flexure regions 504 which provide elasticity. The elasticity allows the conduit 500 to accommodate artery constriction and variation in the internal diameter of the artery. The loop 502 provides axial and radial support to prevent migration of the conduit 500.

Conduit with Rotating Sheath and Deployable Flanges

FIGURES 48A and **48B** illustrate yet another embodiment of a conduit 510, having deployable flanges 514 used to anchor the conduit 510 in place. The conduit 510 includes a sheath 516 which is rotatable, and flanges 514 that include spring arms 512. The sheath 516 has windows 518 through which the flanges 514 are deployed. Prior to positioning in the body, the sheath 516 is positioned on the conduit 510 so as to retain the flanges 514. After the conduit 510 is properly positioned, the sheath 516 is rotated such that the windows 518 are aligned with the flanges 514. The spring arms 514 cause the flanges 514 to be deployed through the windows 518 following rotation of the retaining sheath 516, thus anchoring the conduit 510 in its proper position. It should be noted that no axial rotation is required to deploy the flanges 514.

It should be appreciated that the stents and conduits described above, and particularly the bulkhead stent, are useful in other applications in addition to stenting the myocardium. For example, these stents may also serve as other types of coronary stents, arterial or venous stents, as well as billiary and esophageal stents.

The present vascular shunt provides significant improvements in the present treatment of blockages in the coronary artery. Although the invention has been described in its preferred embodiments in connection with the particular figures, it is not intended that this description should be limited in any way.

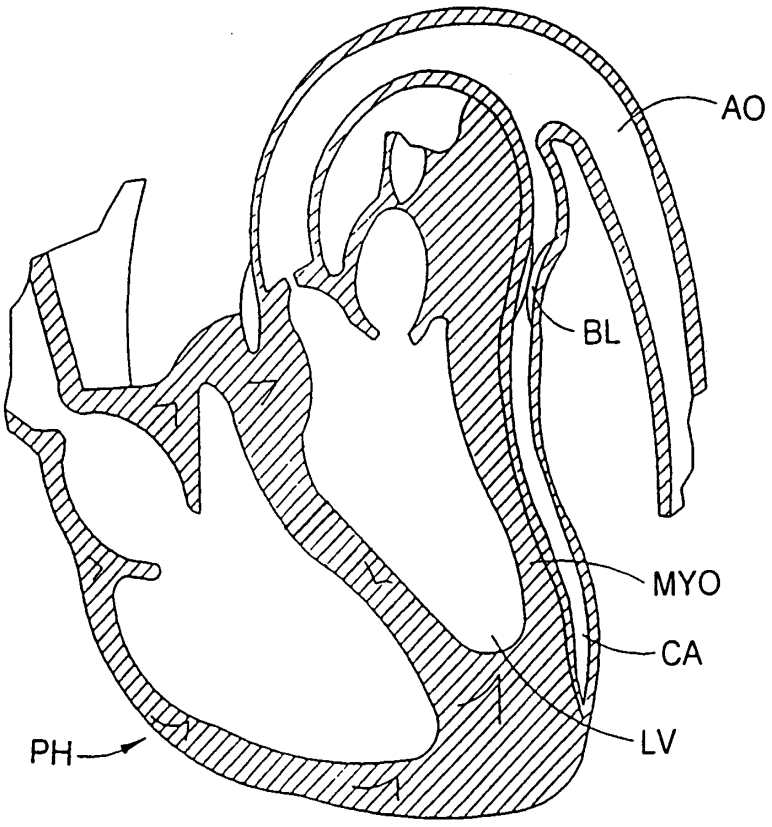


FIG. 1A

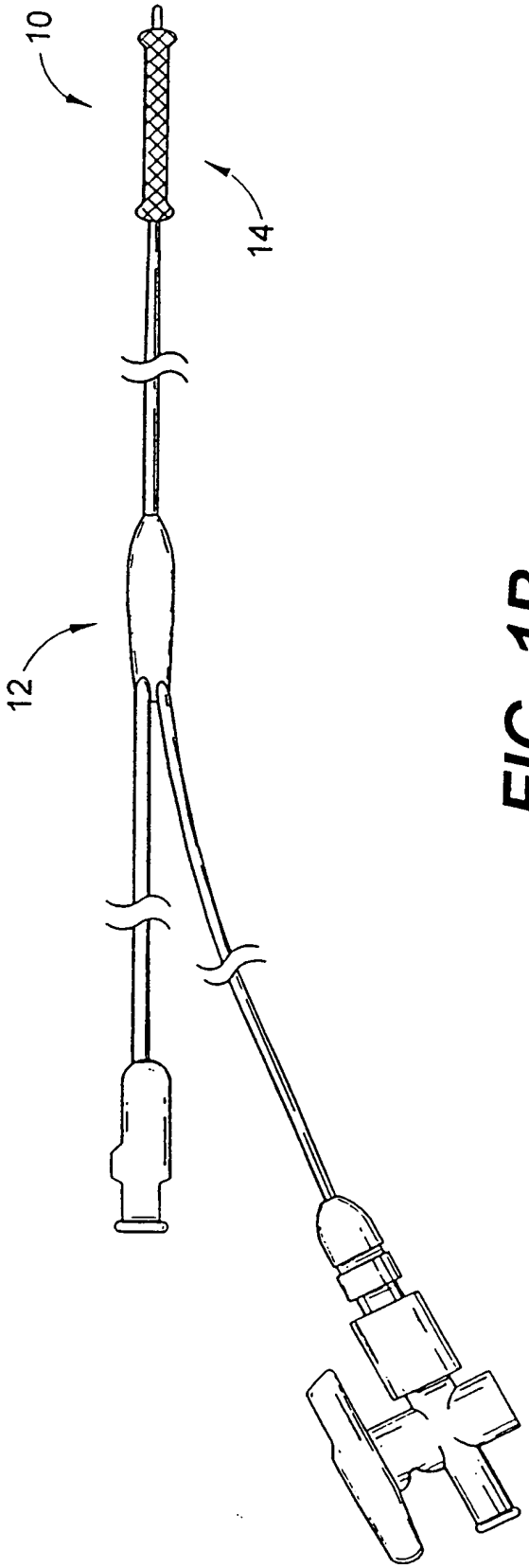


FIG. 1B

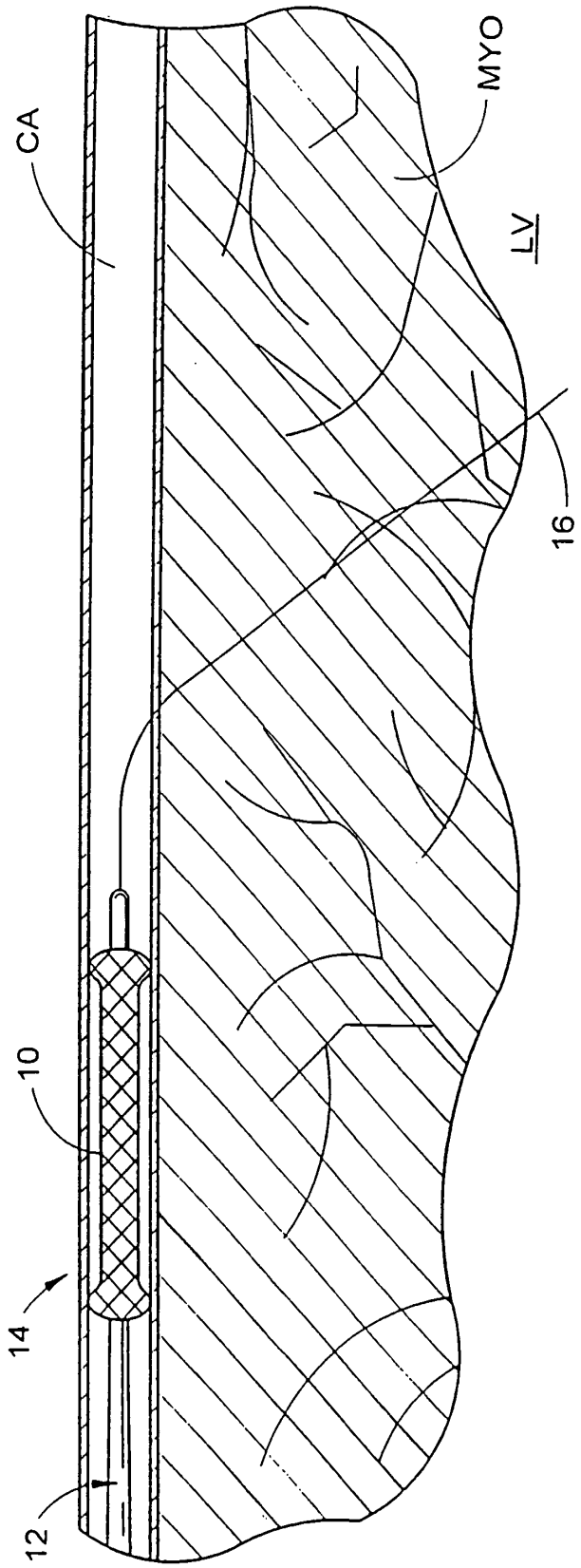


FIG. 2

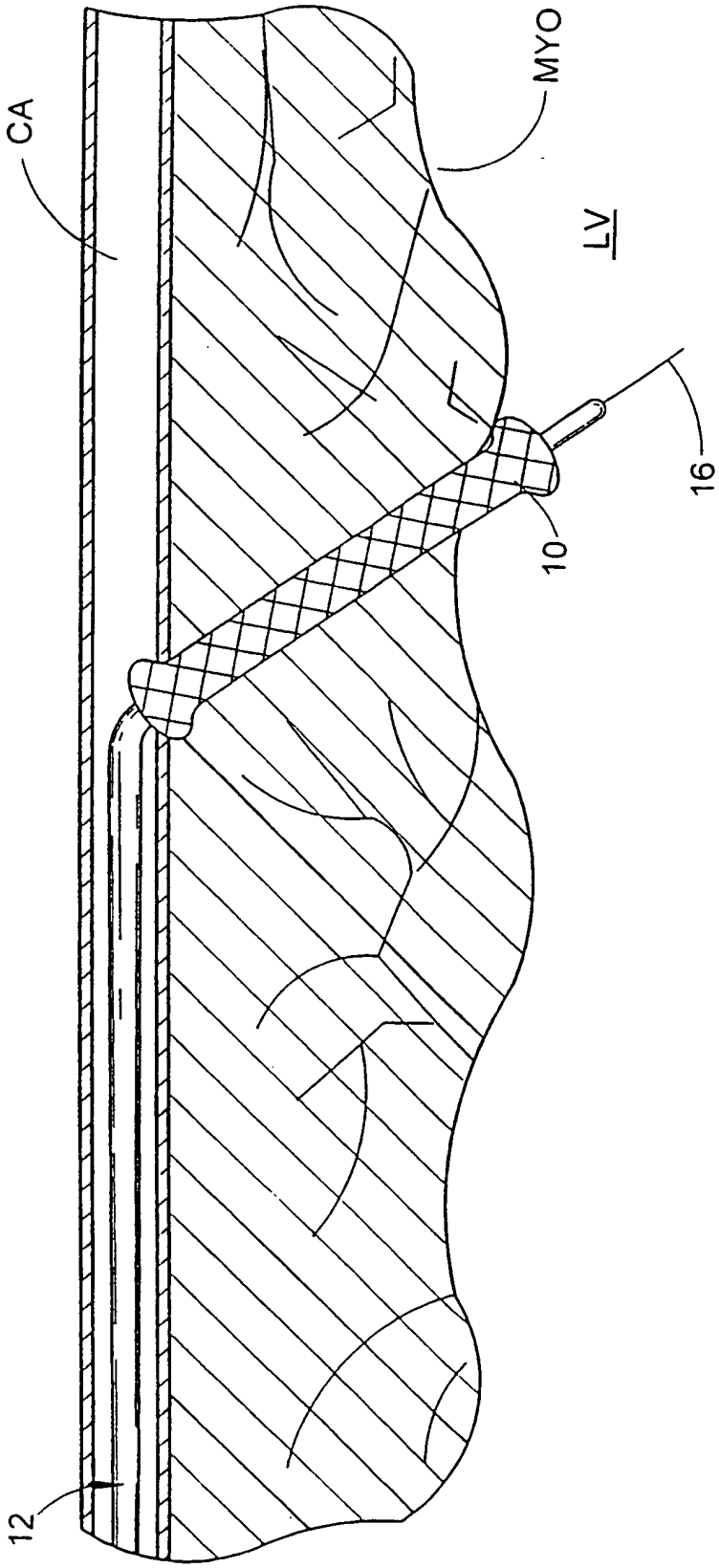


FIG. 3

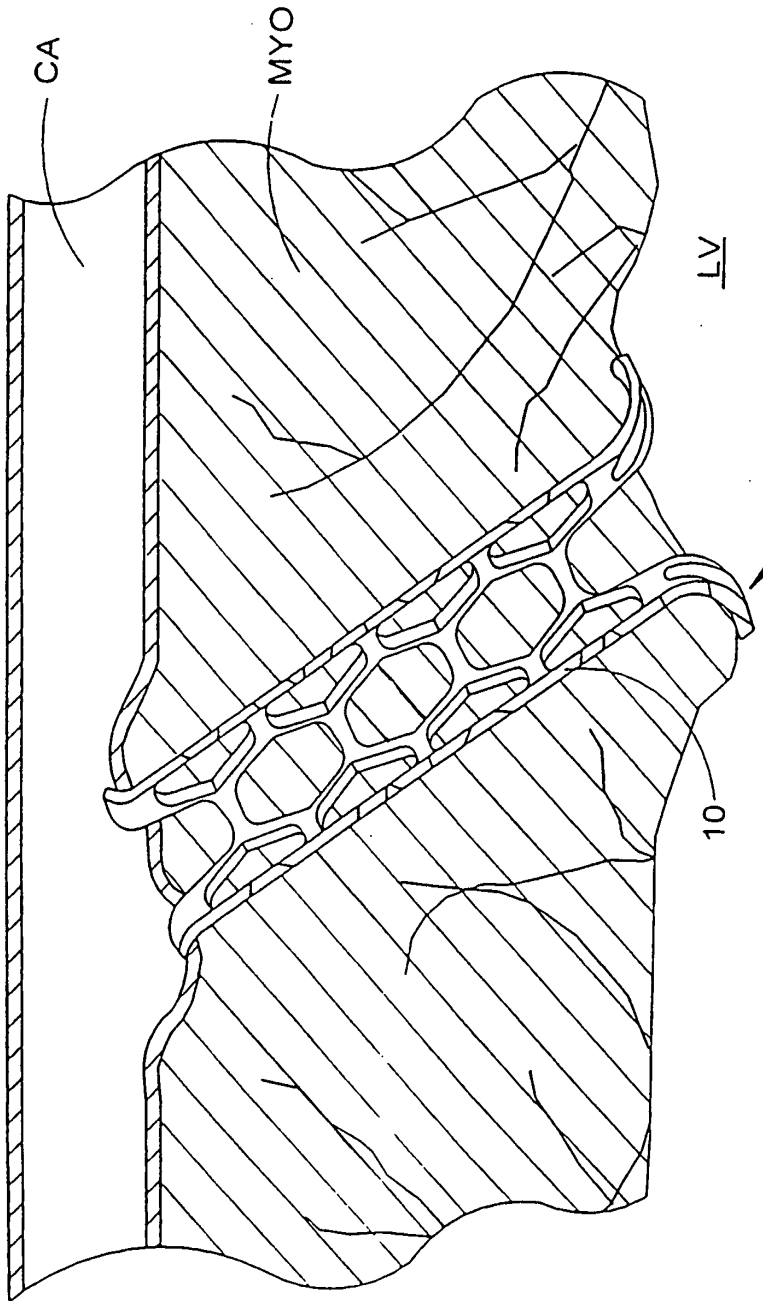


FIG. 4

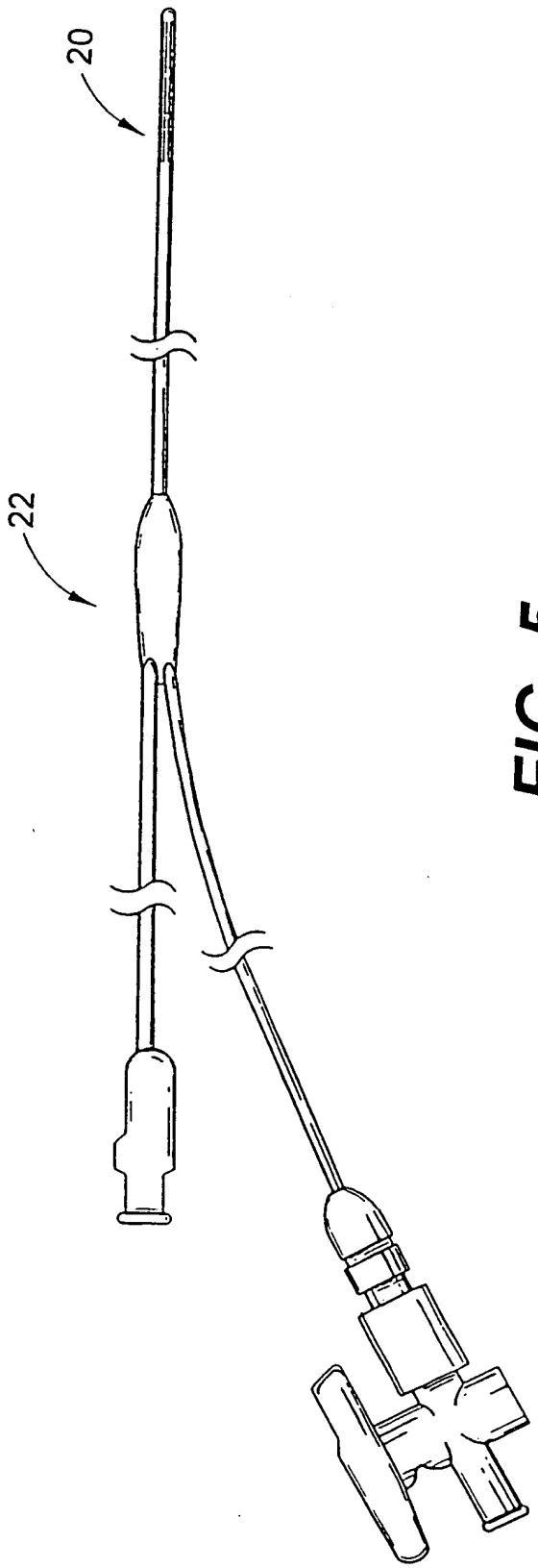


FIG. 5

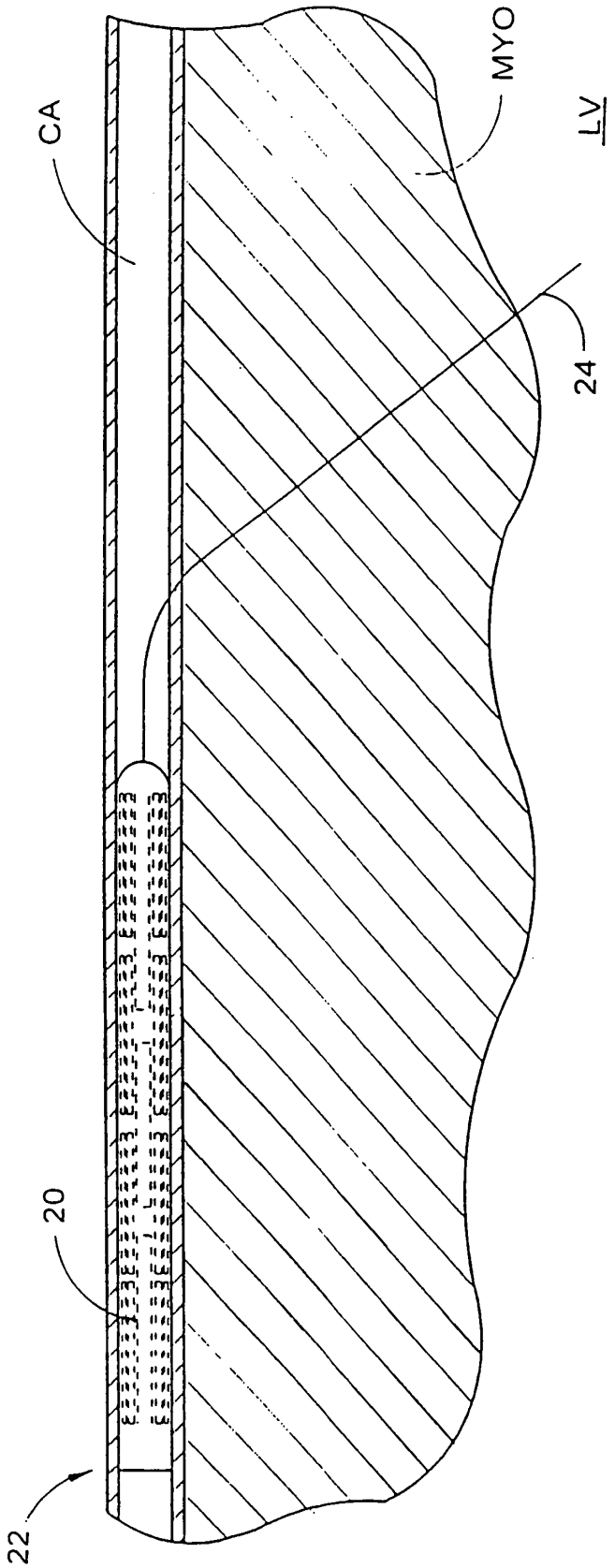


FIG. 6

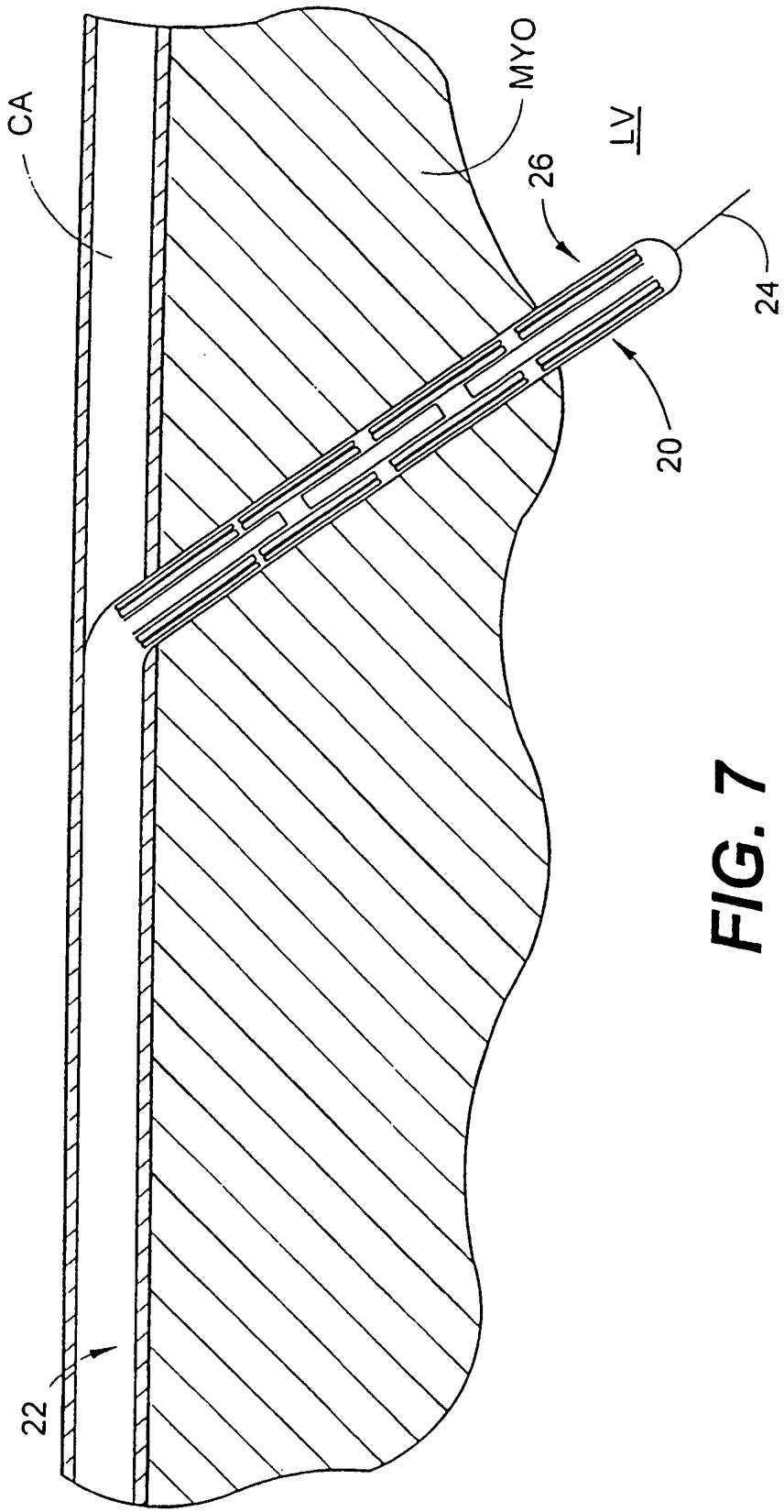


FIG. 7

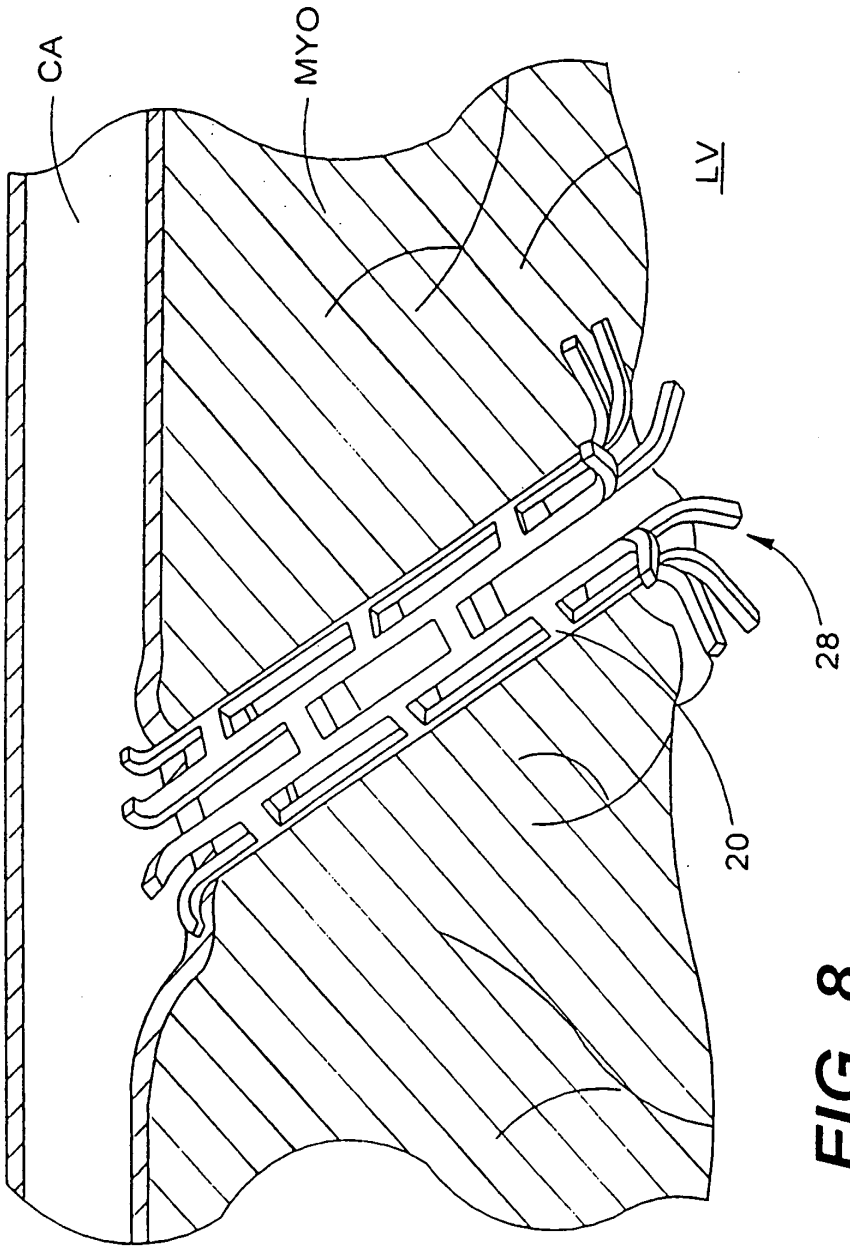


FIG. 8

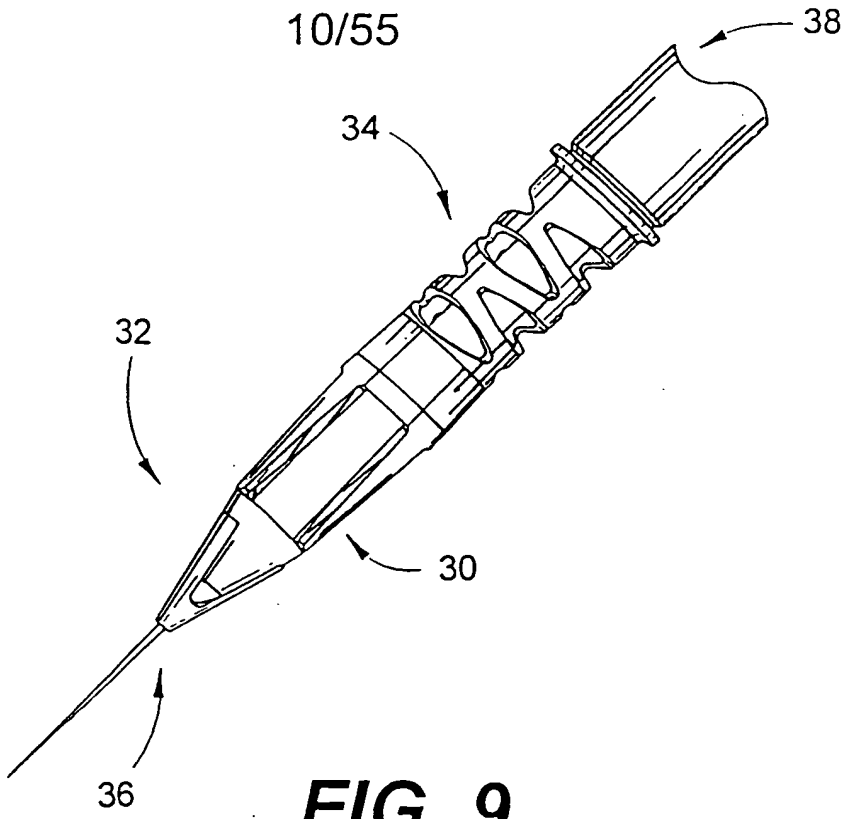


FIG. 9

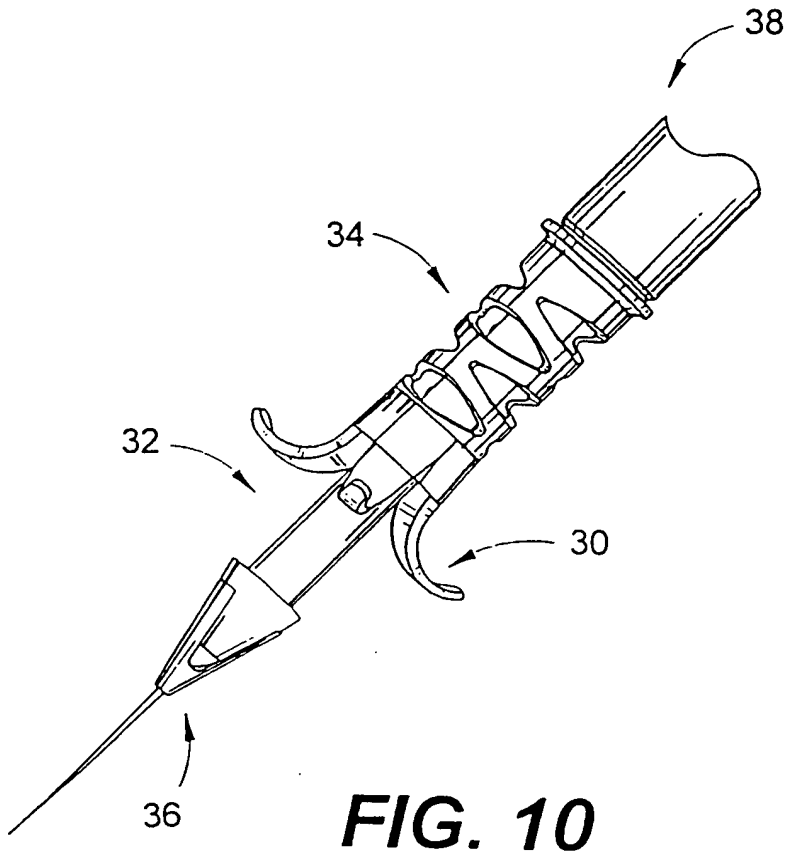


FIG. 10

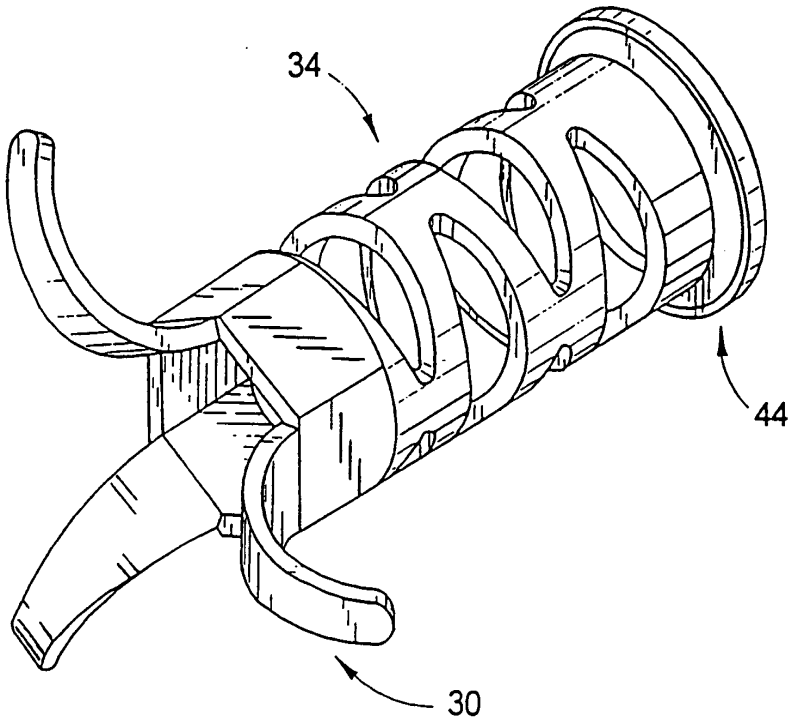


FIG. 11

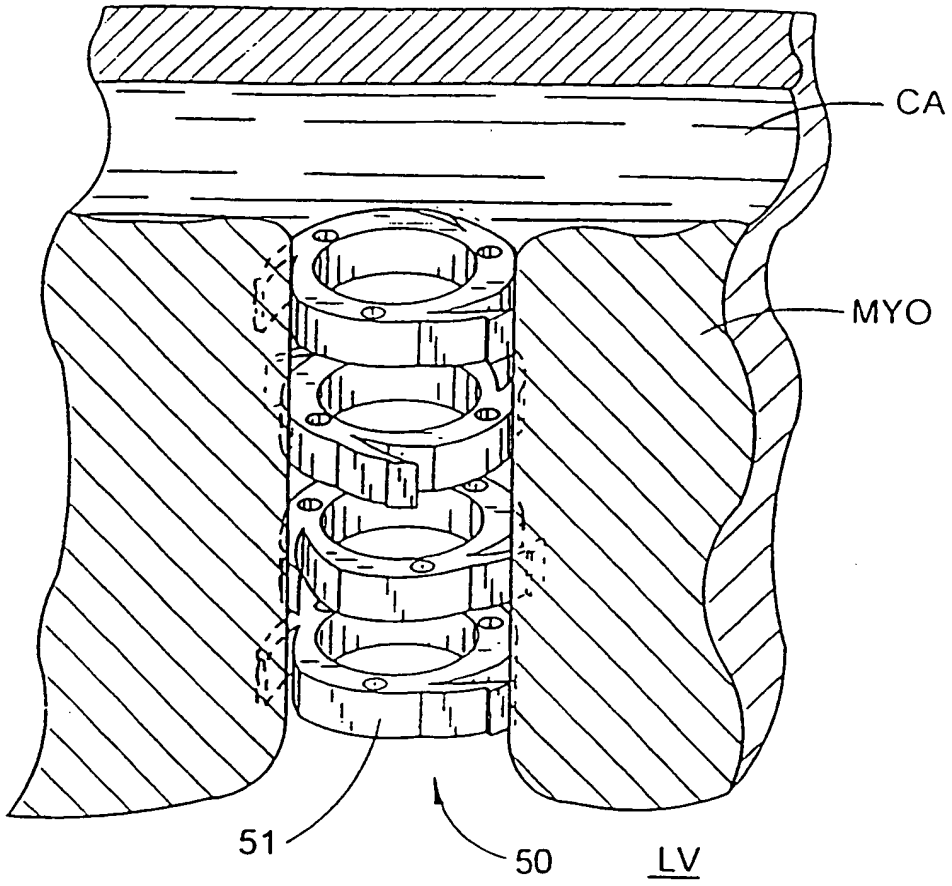


FIG. 12

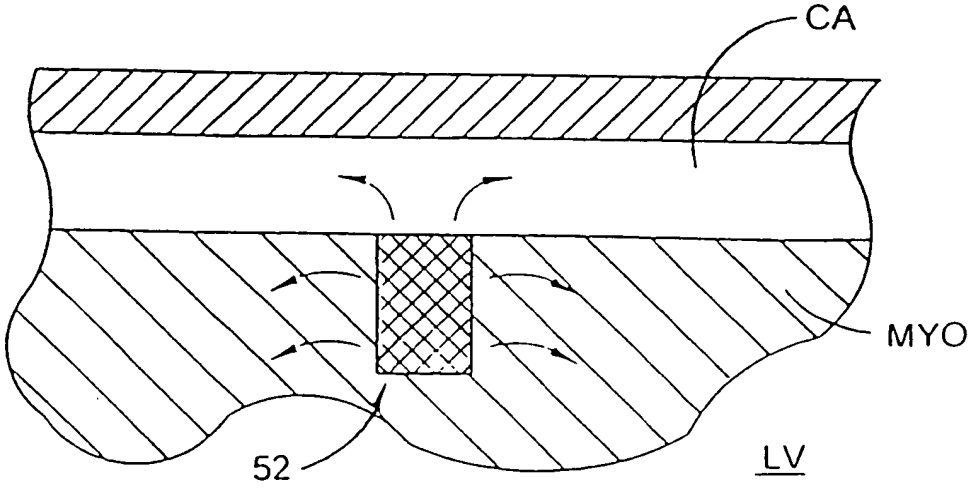


FIG. 13

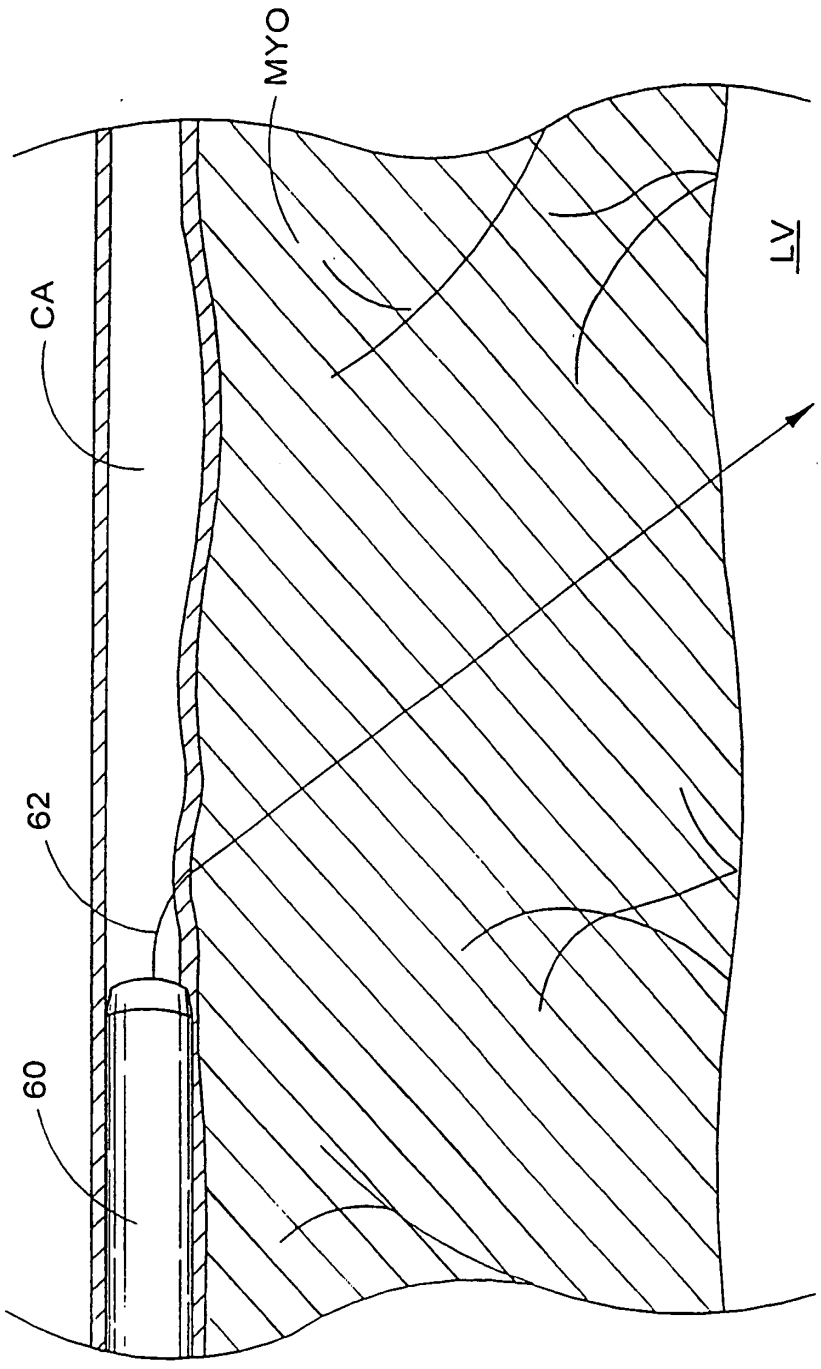


FIG. 14

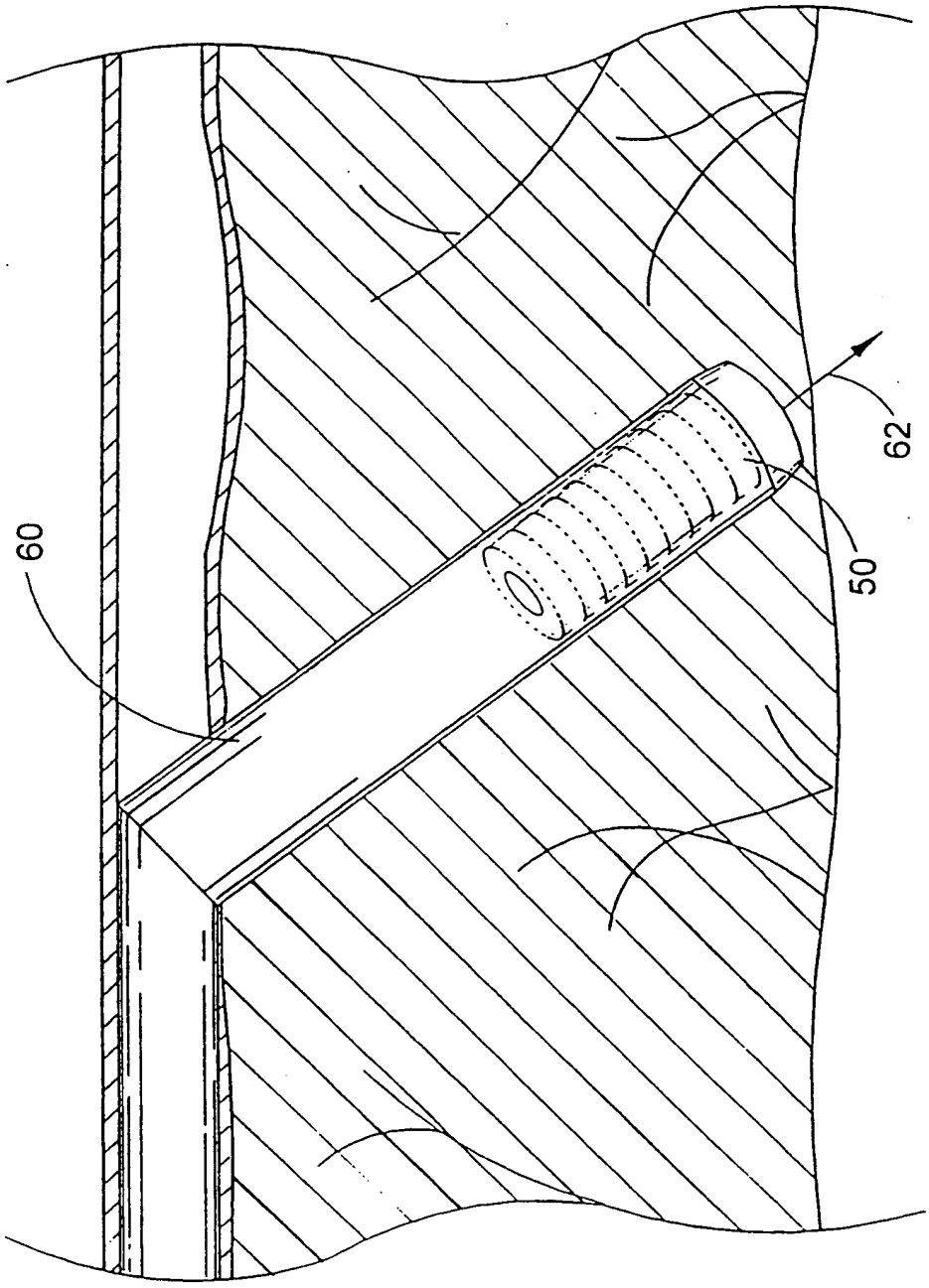


FIG. 15

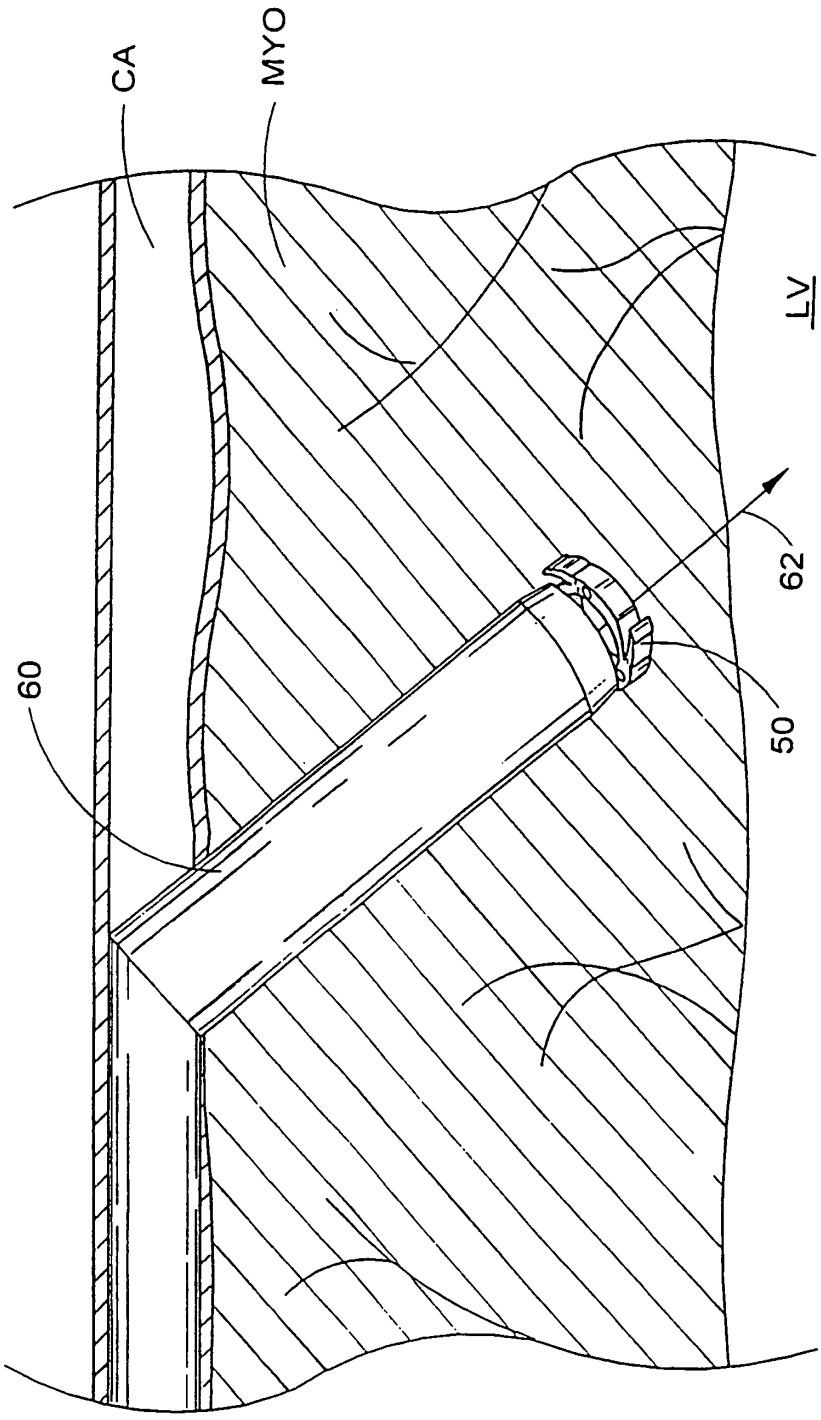


FIG. 16

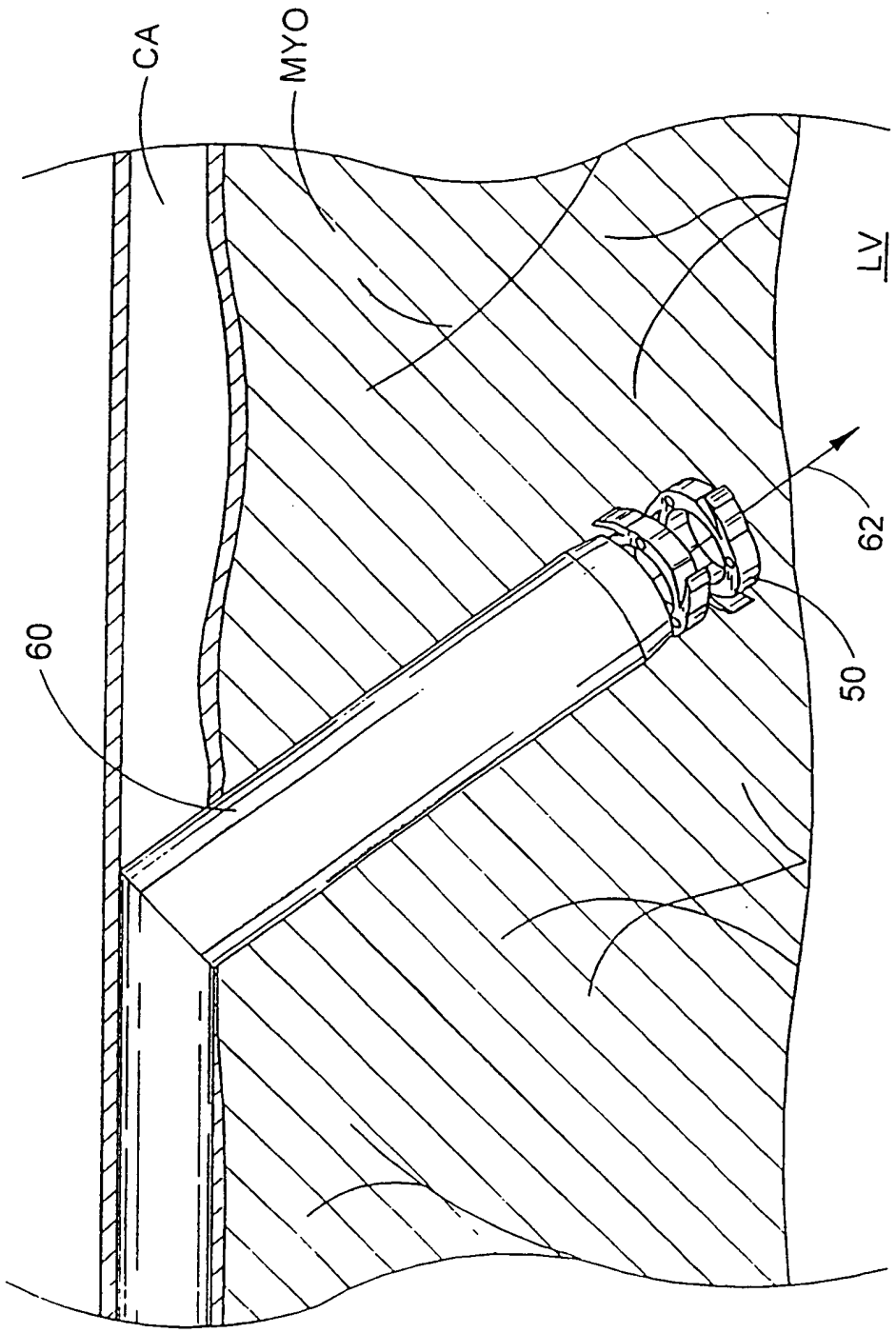


FIG. 17

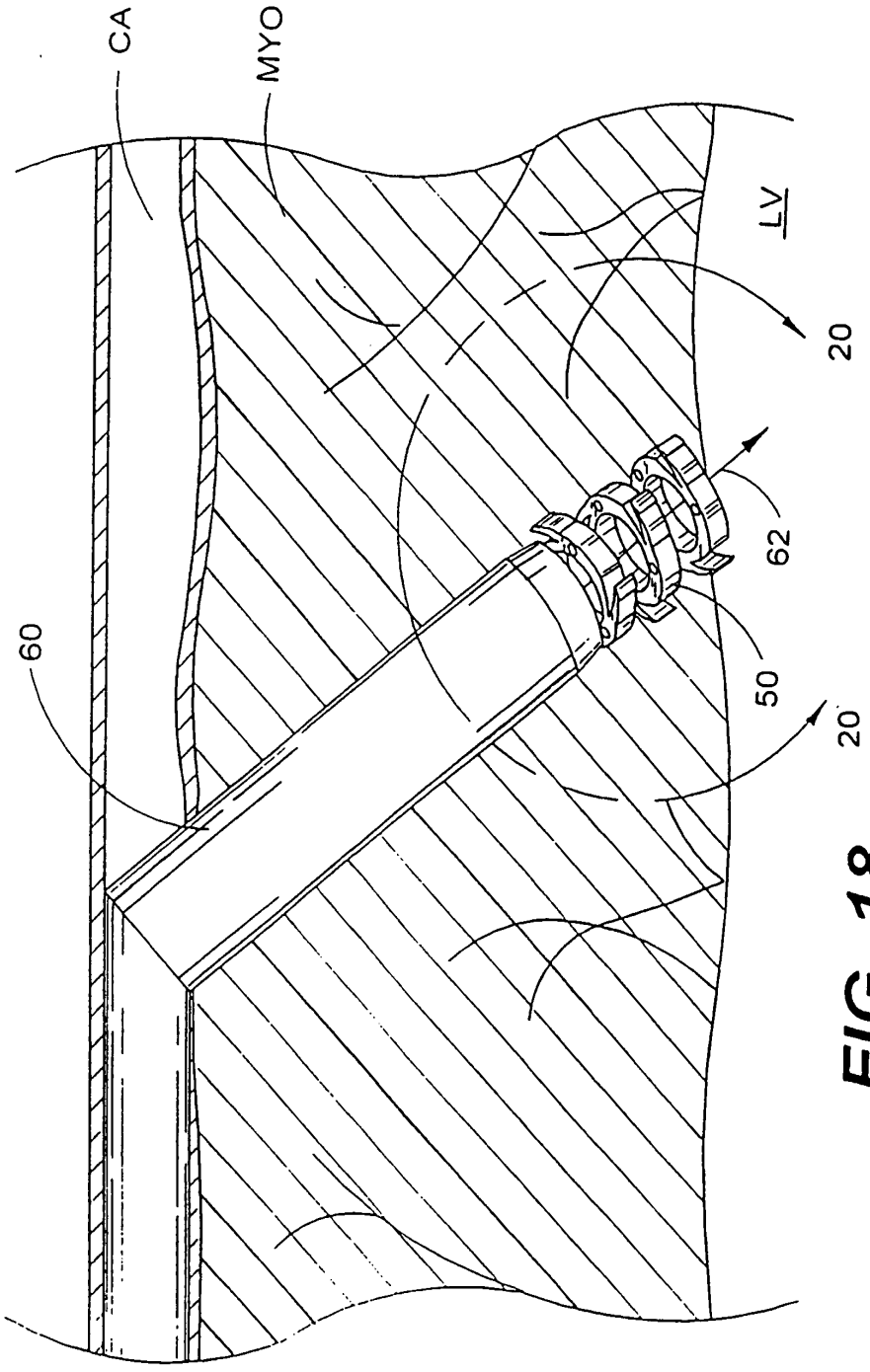


FIG. 18

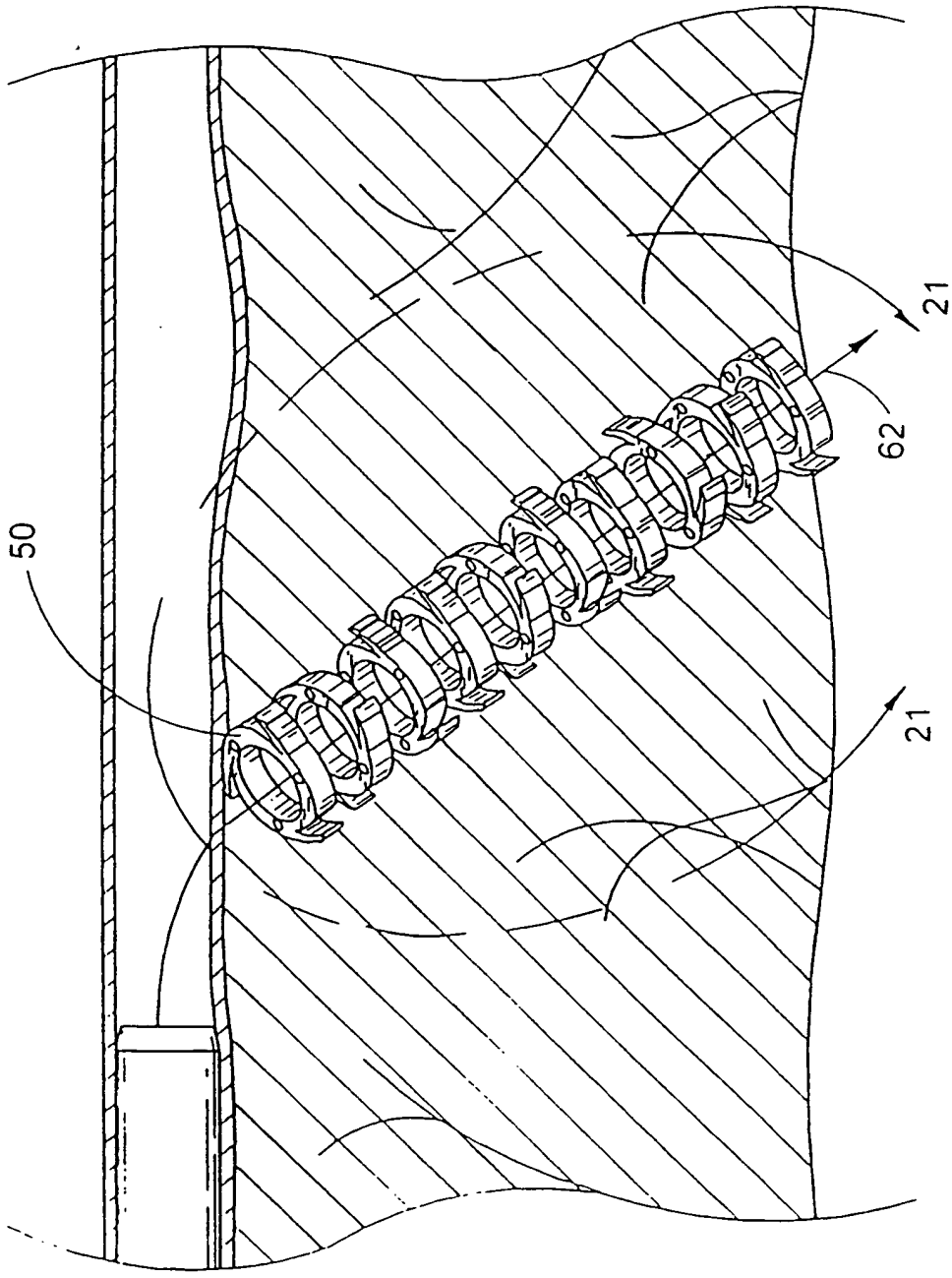


FIG. 19

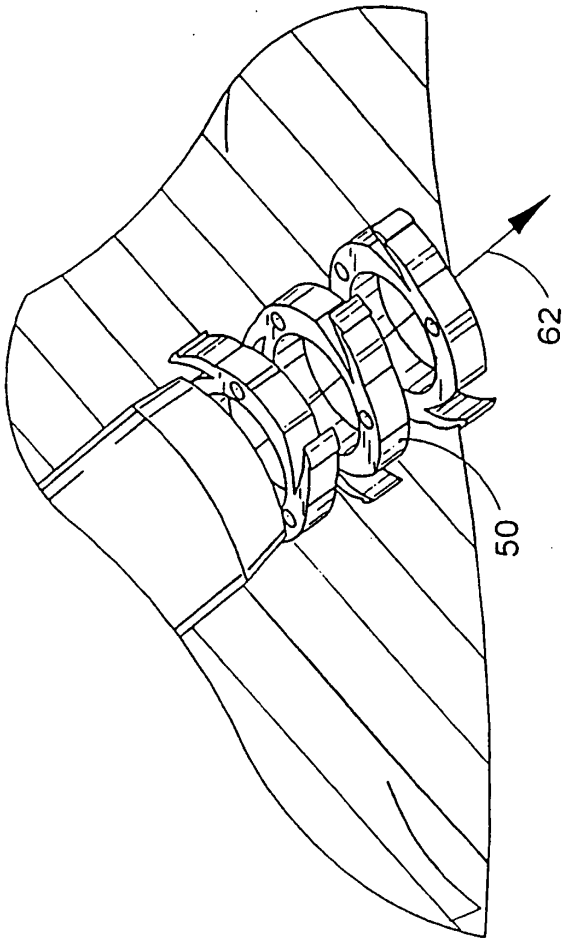


FIG. 20

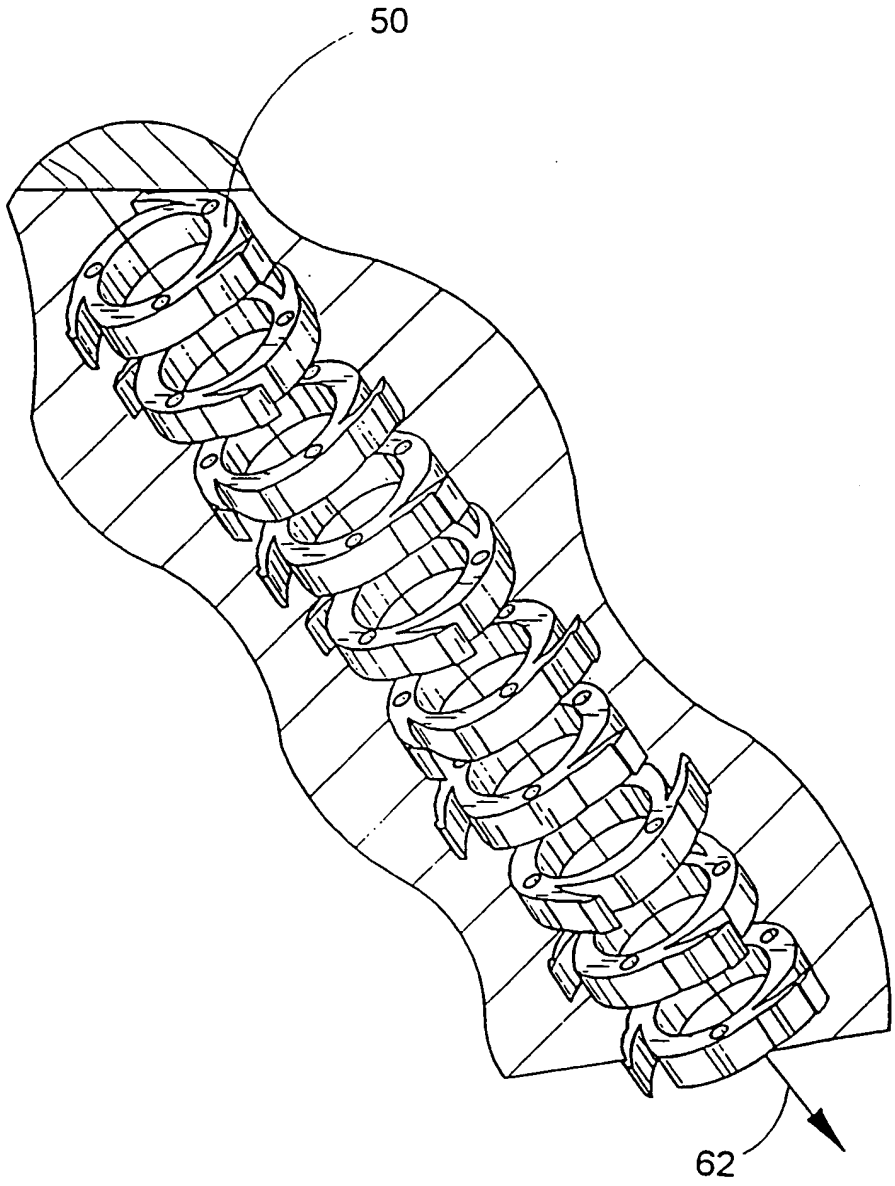


FIG. 21

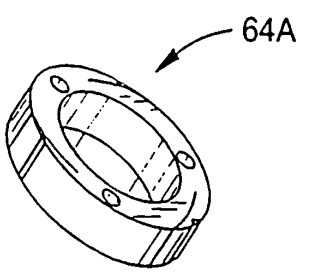


FIG. 22

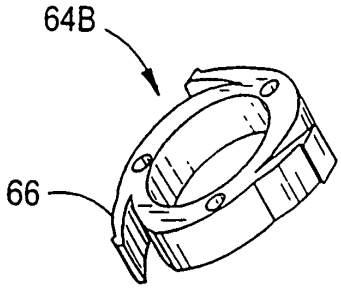


FIG. 23

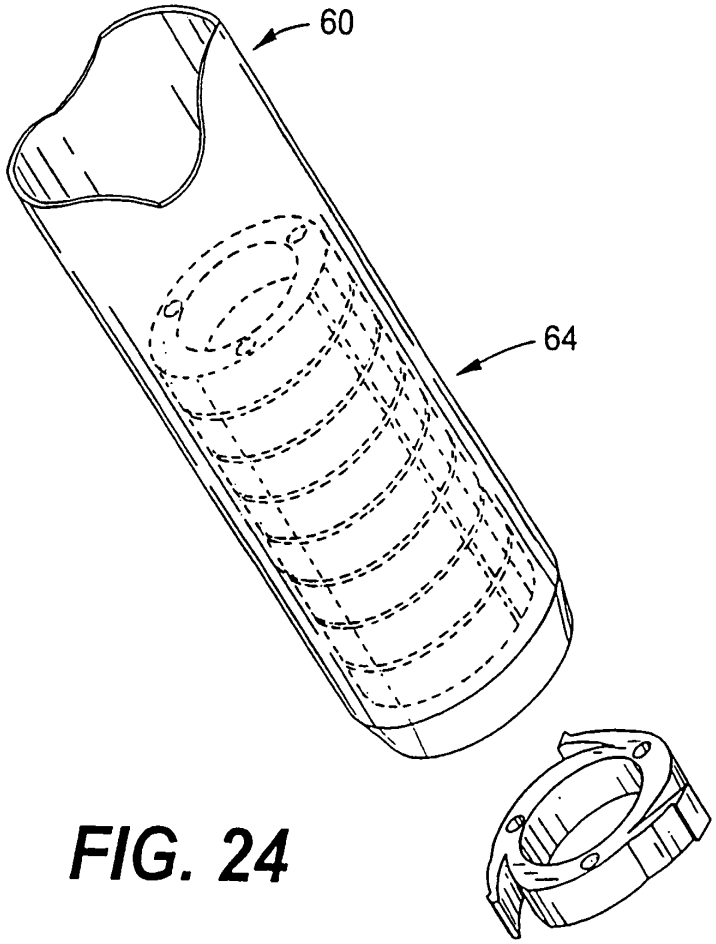


FIG. 24

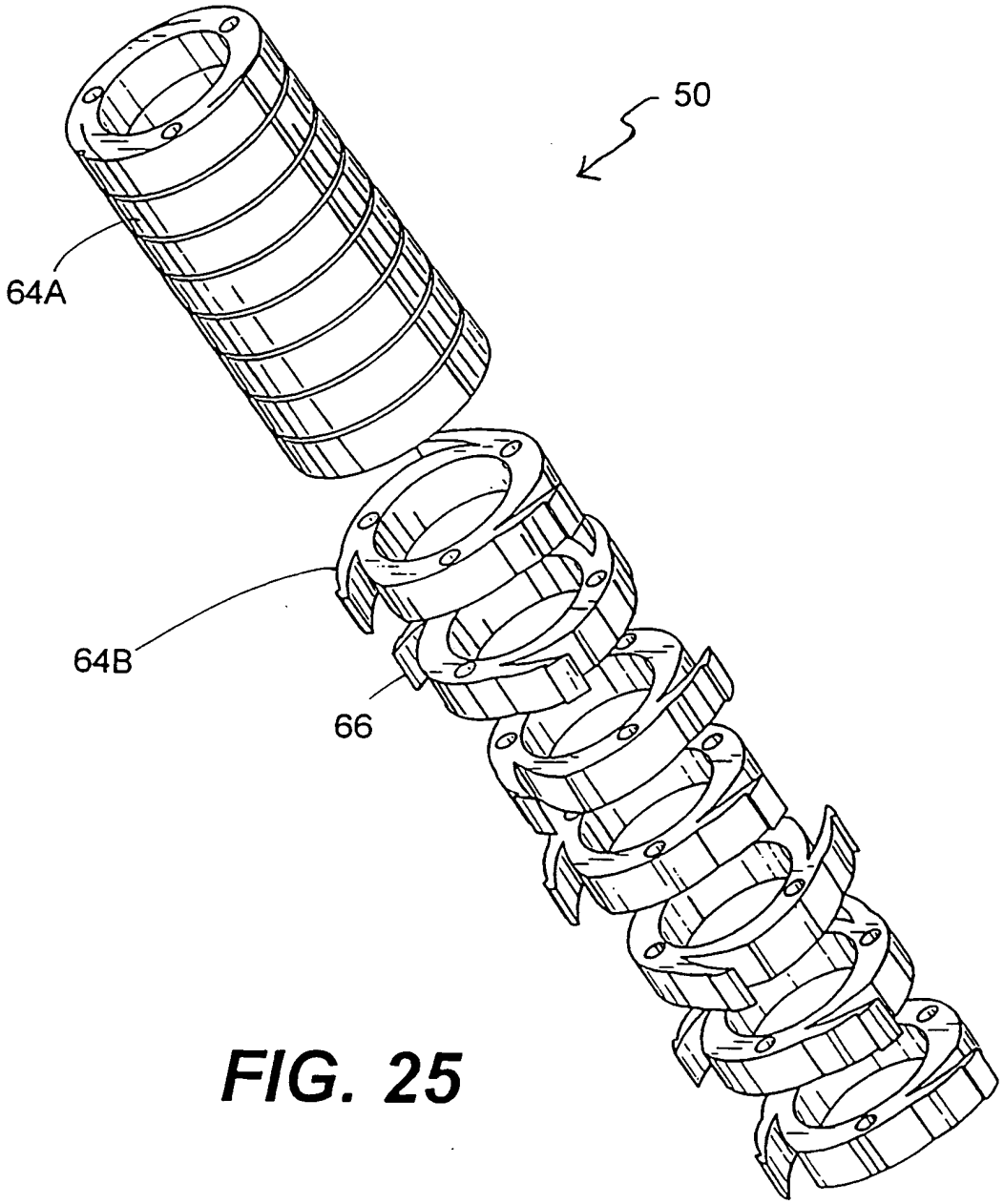


FIG. 25

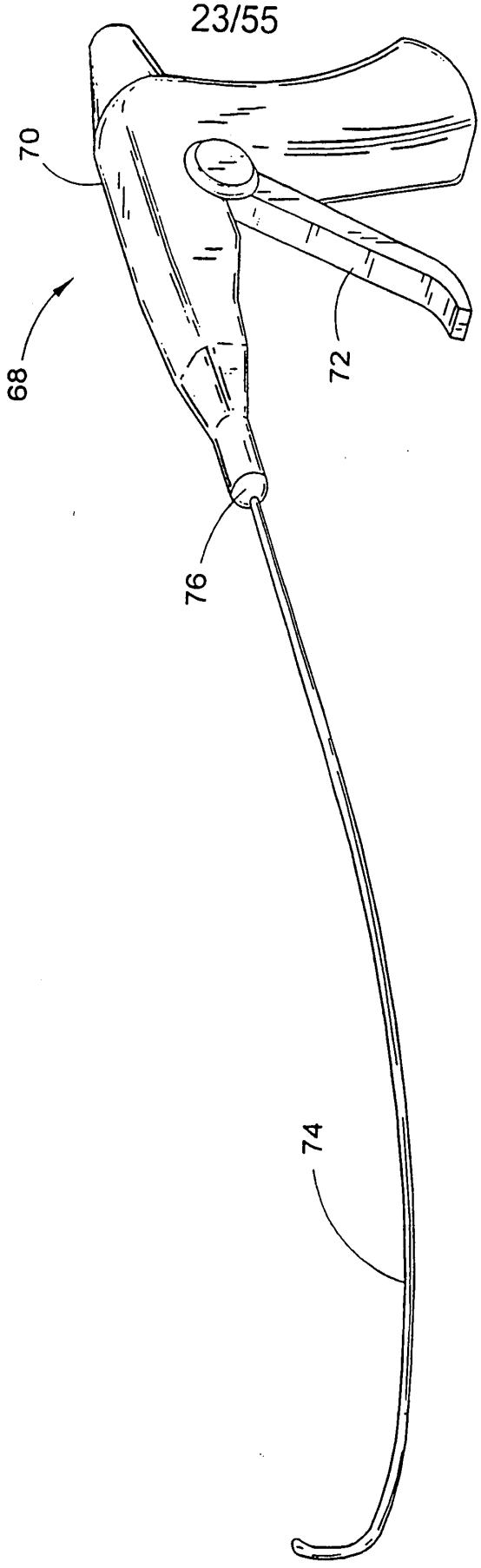


FIG. 26

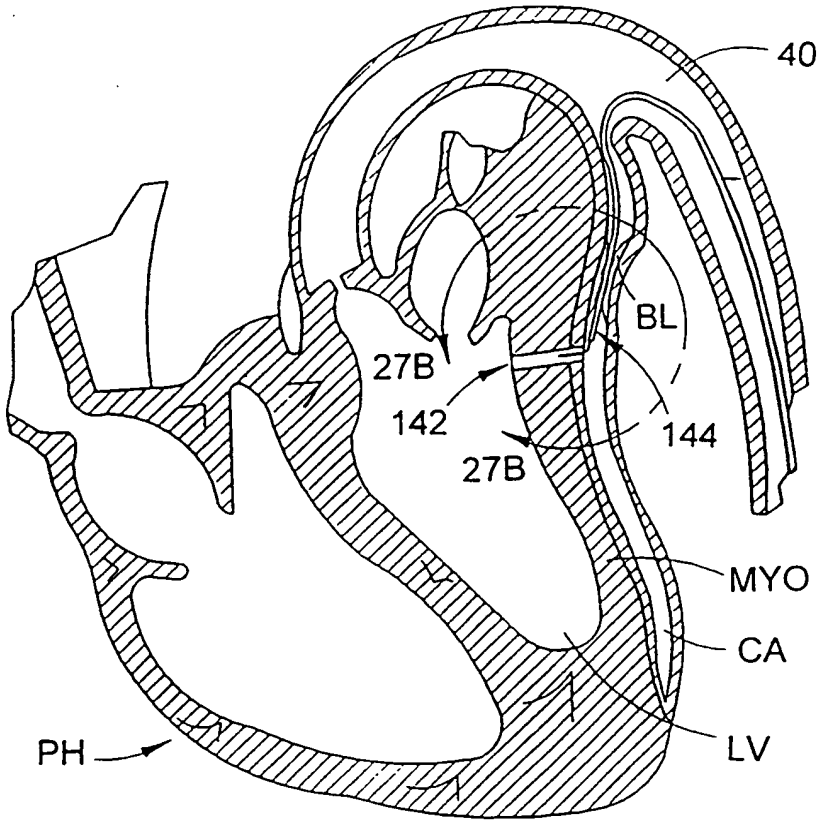


FIG. 27A

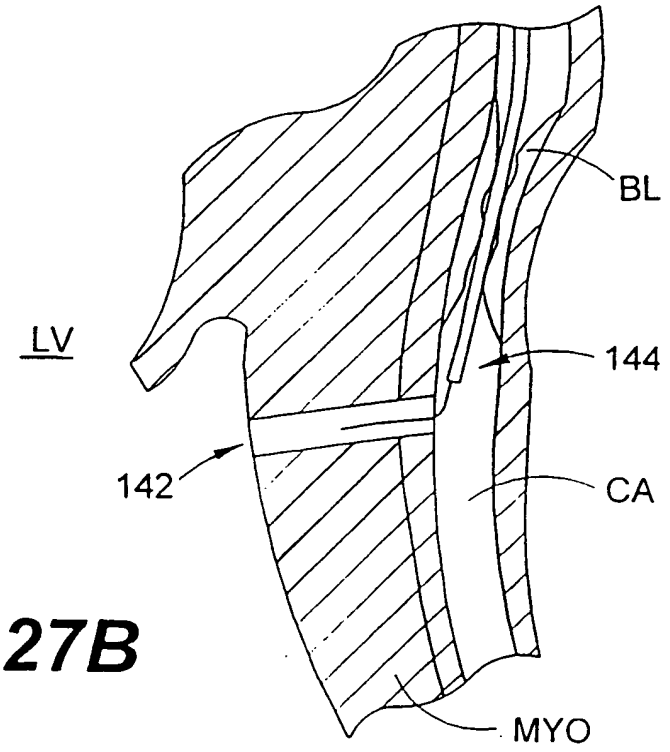
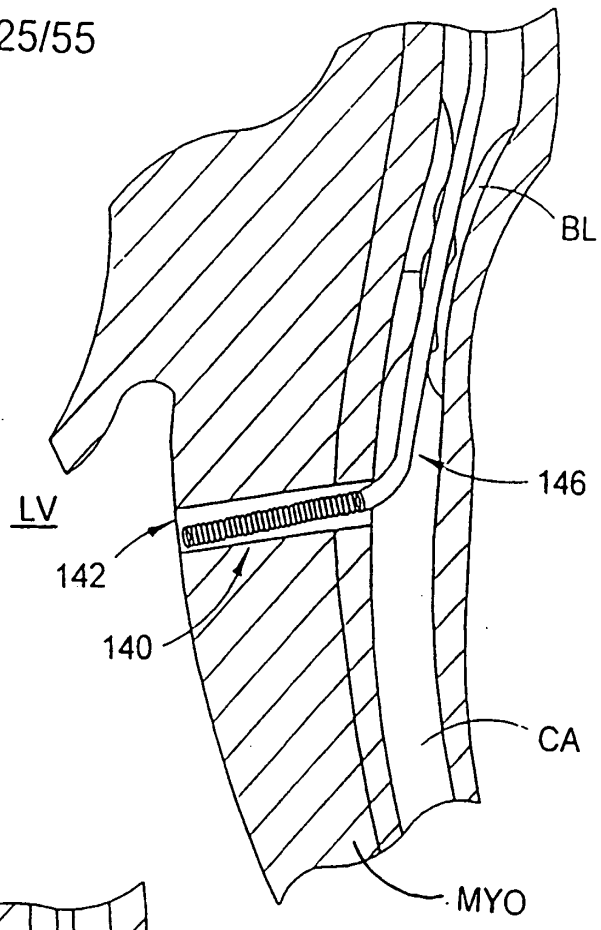


FIG. 27B

FIG. 28



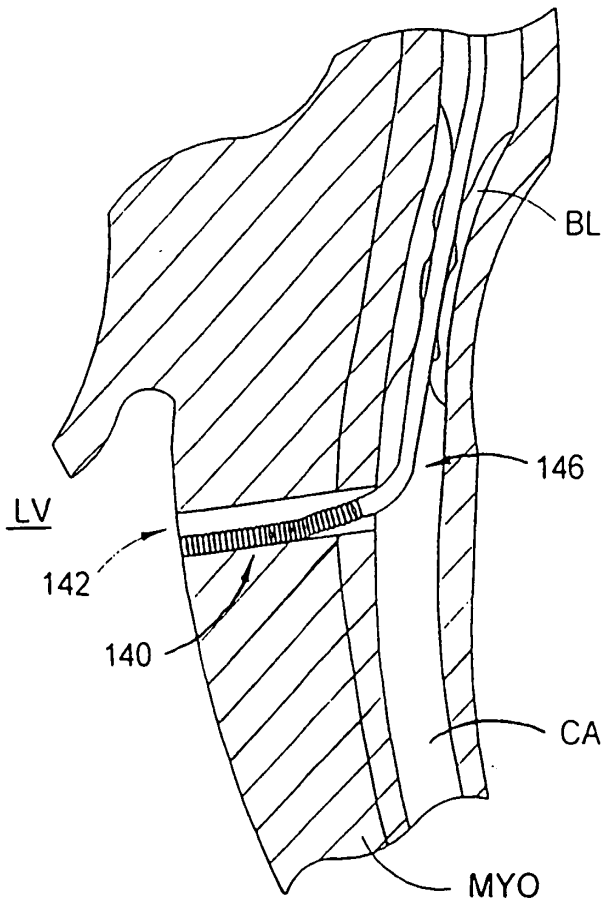


FIG. 29

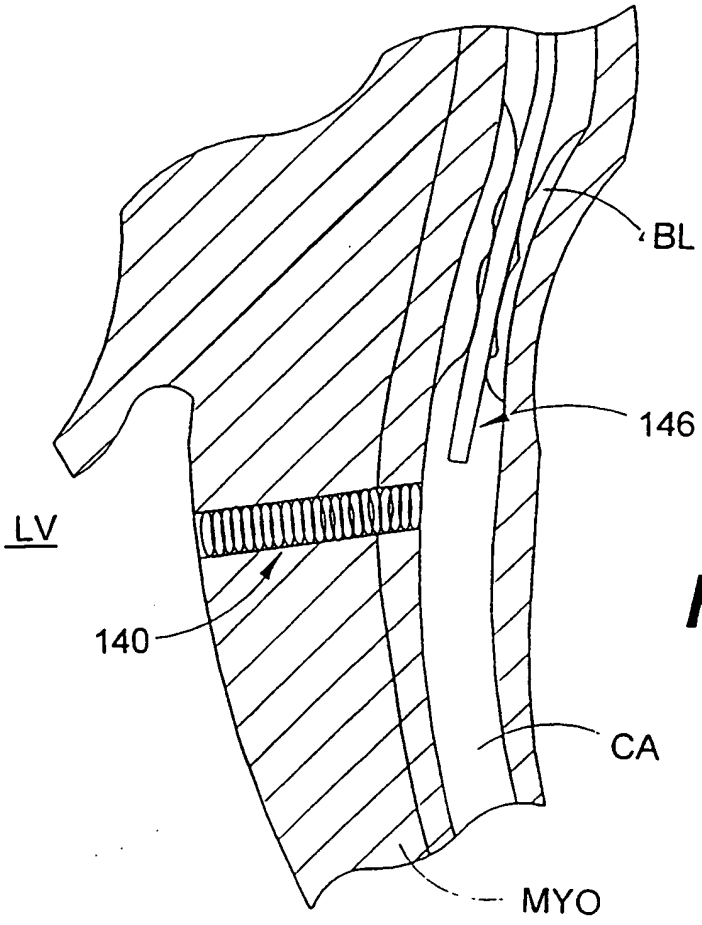


FIG. 30

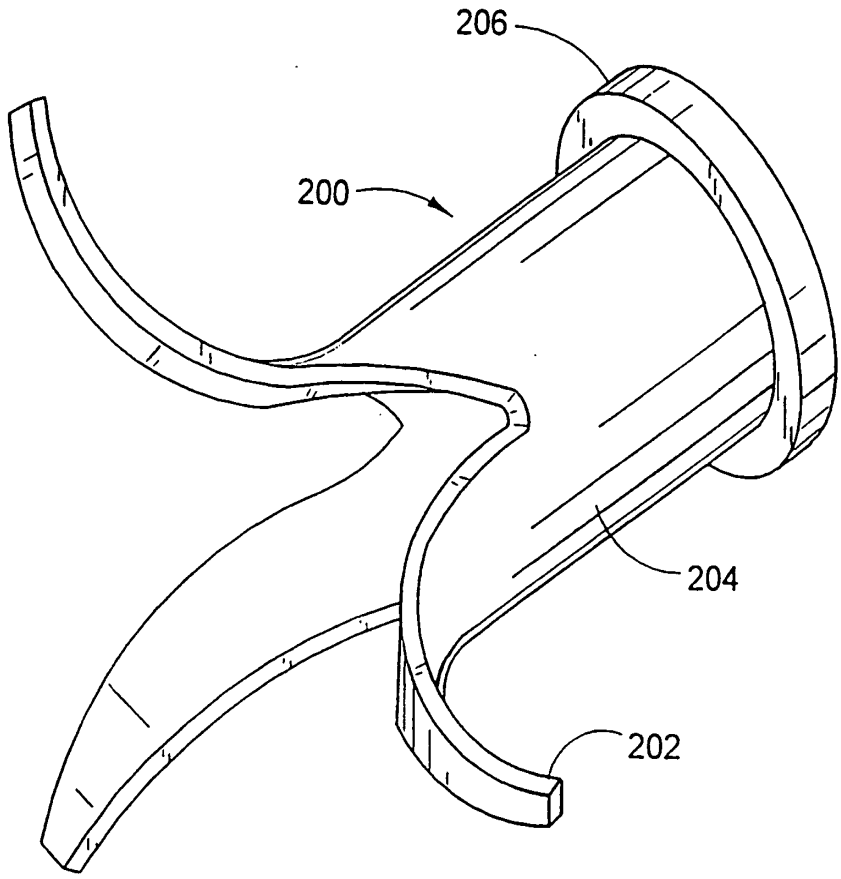


FIG. 31

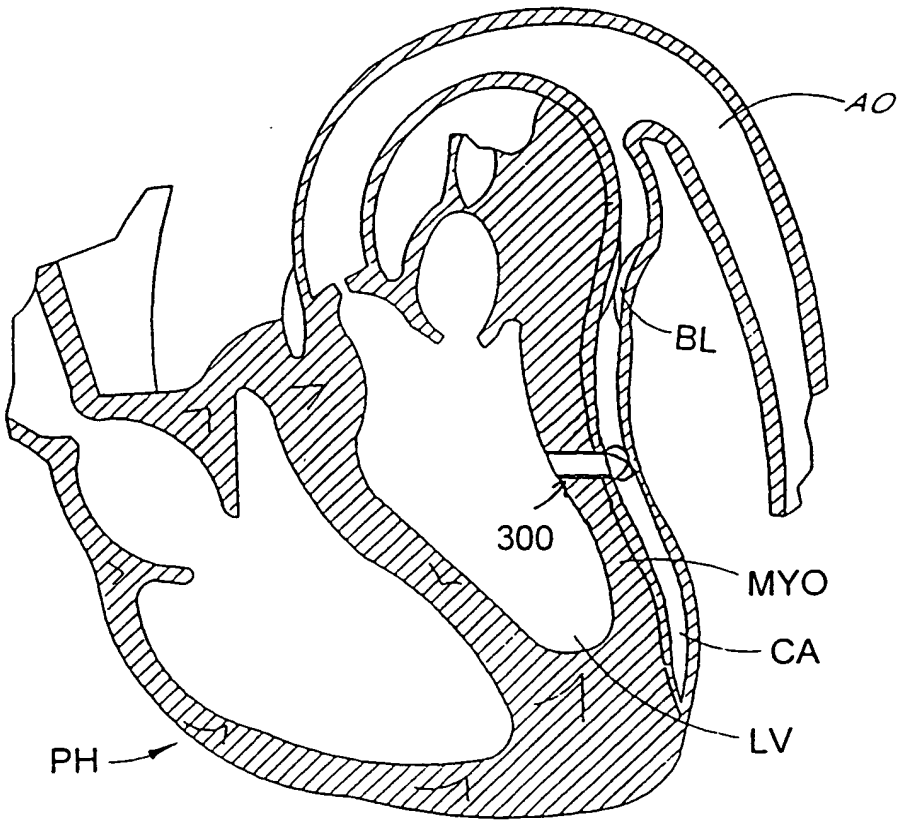


FIG. 32

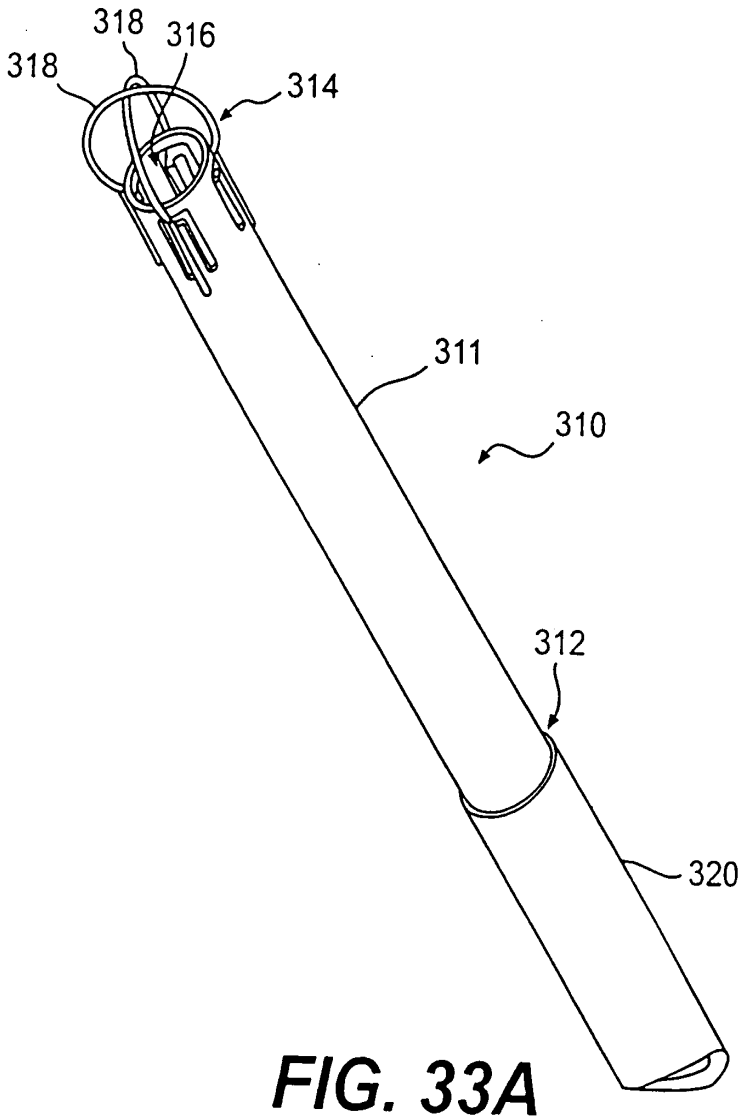


FIG. 33A

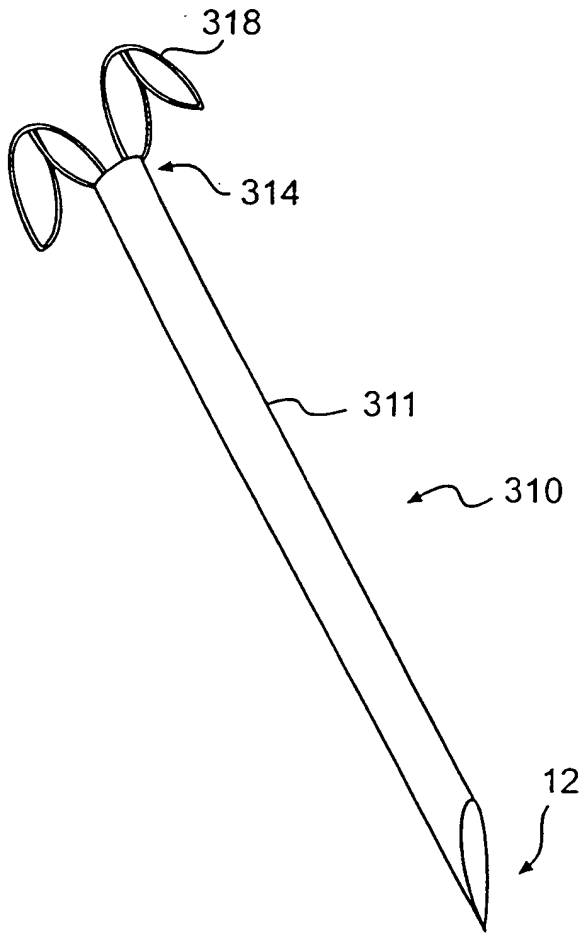


FIG. 33B

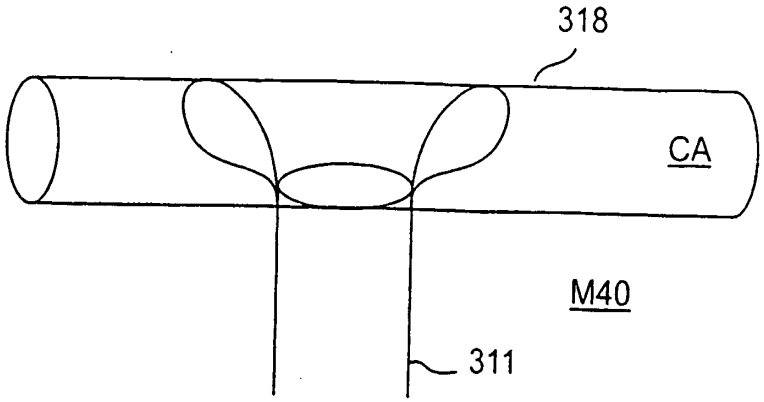


FIG. 33C

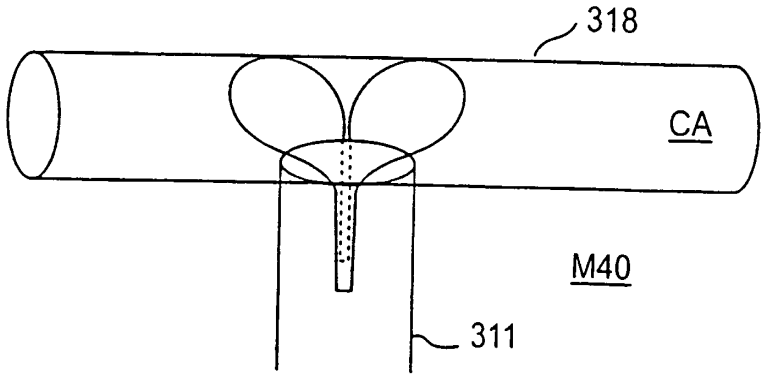


FIG. 33D

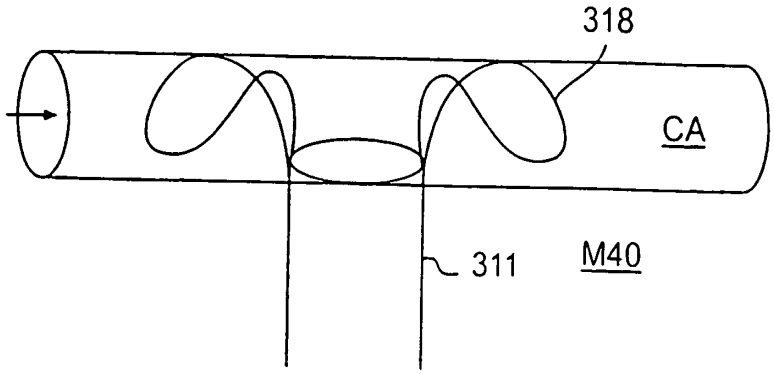


FIG. 33E

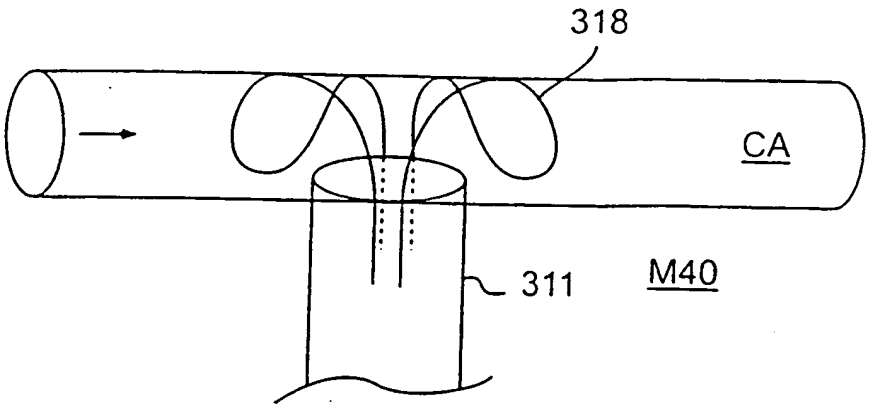


FIG. 33F

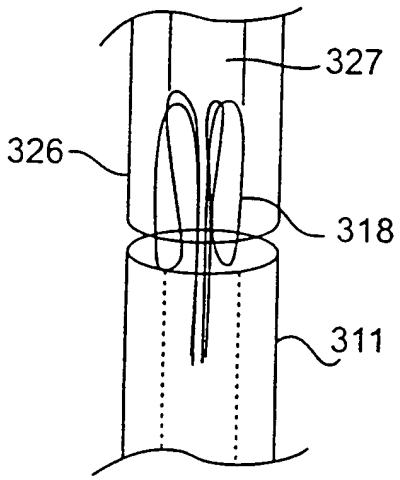


FIG. 33G

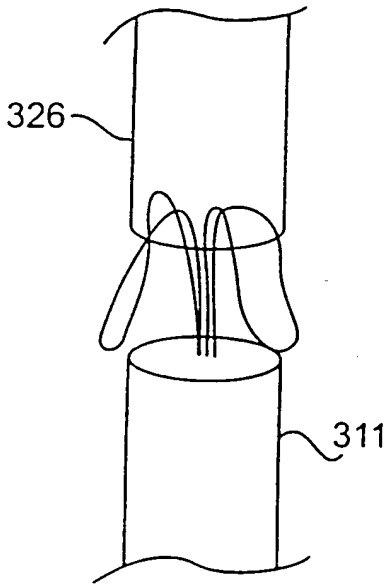


FIG. 33H

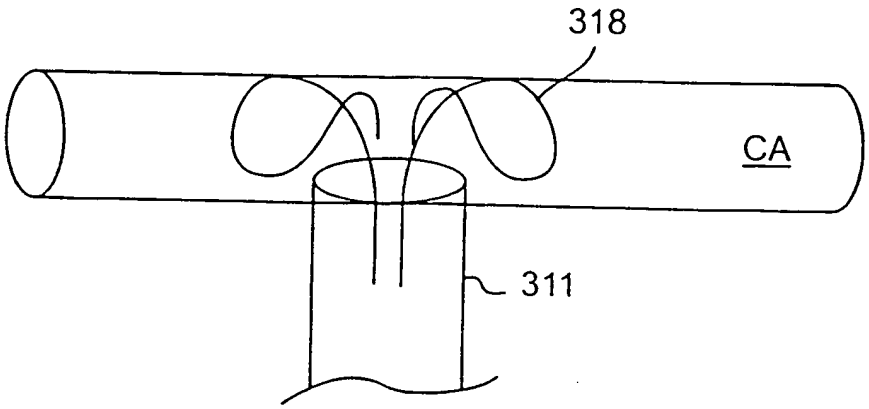


FIG. 33I

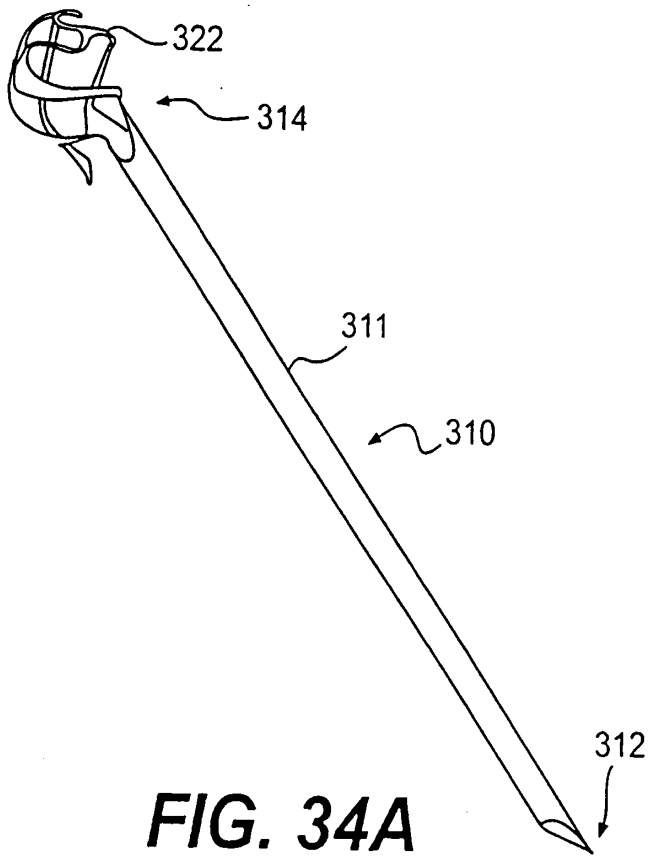


FIG. 34A

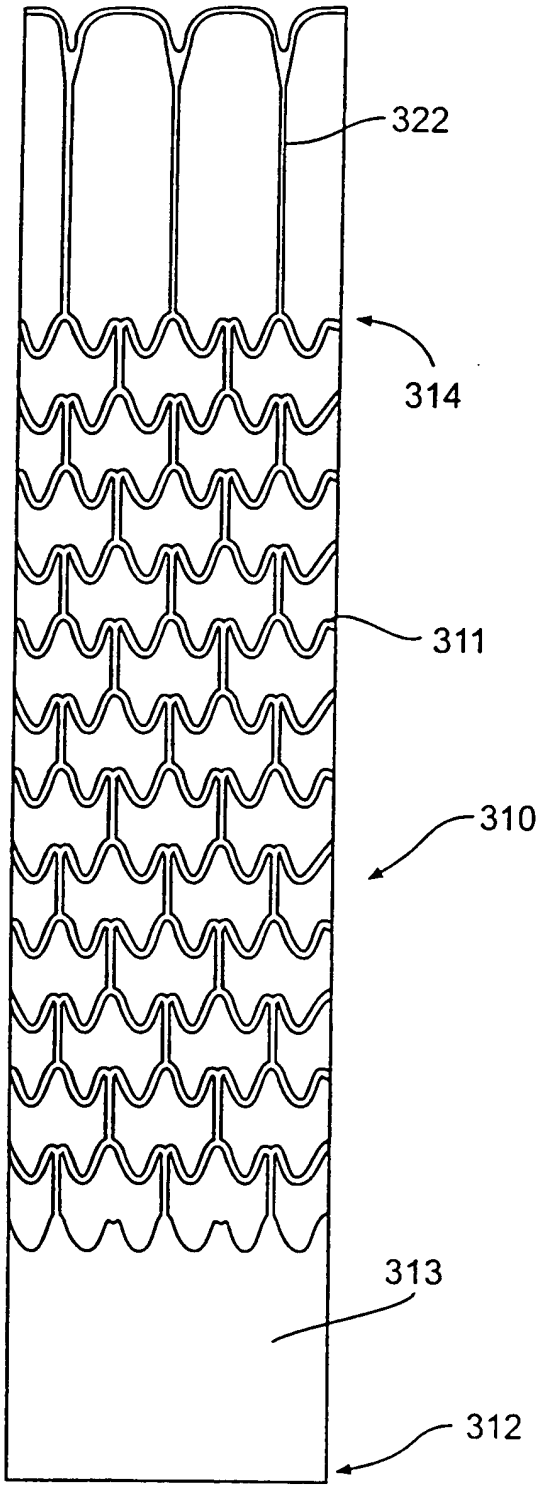


FIG. 34B

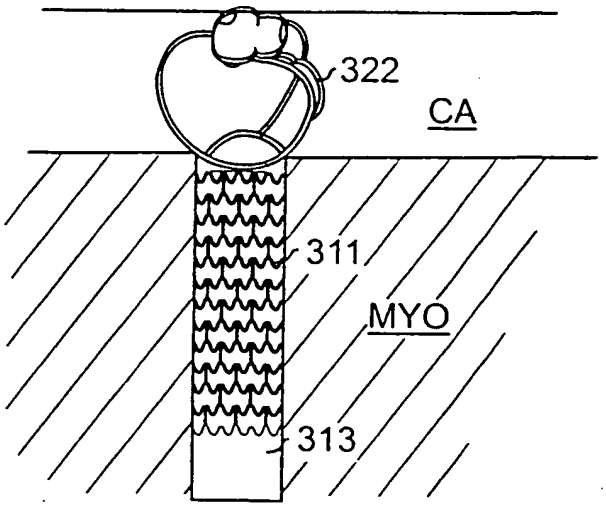


FIG. 34C

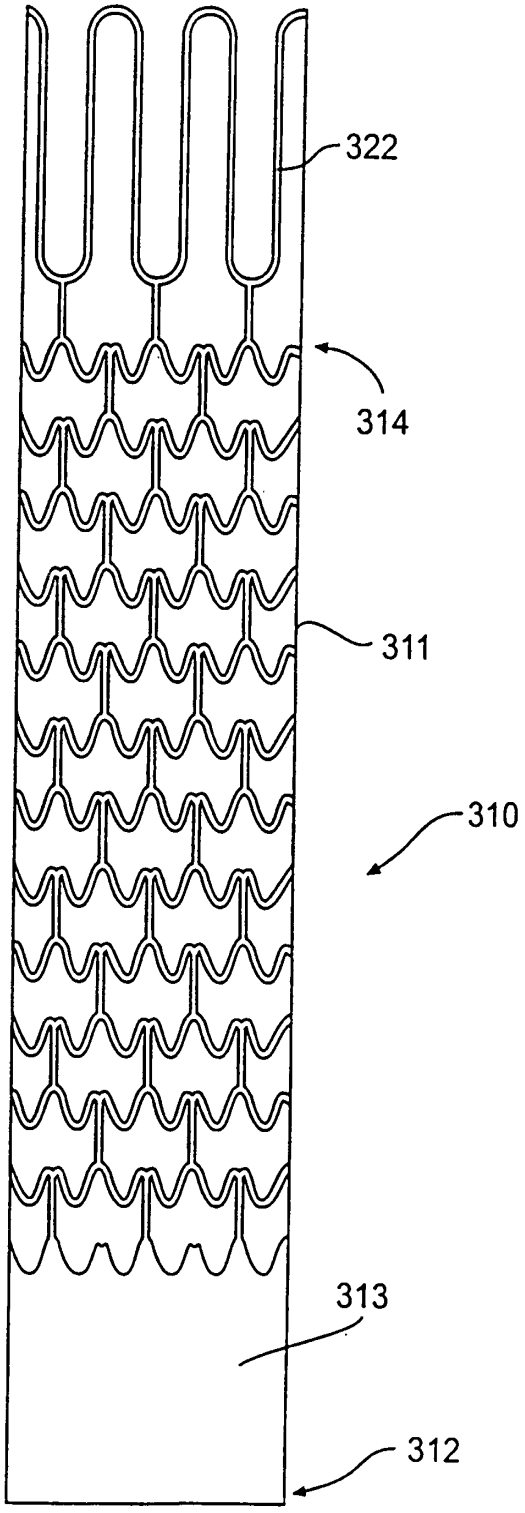


FIG. 34D

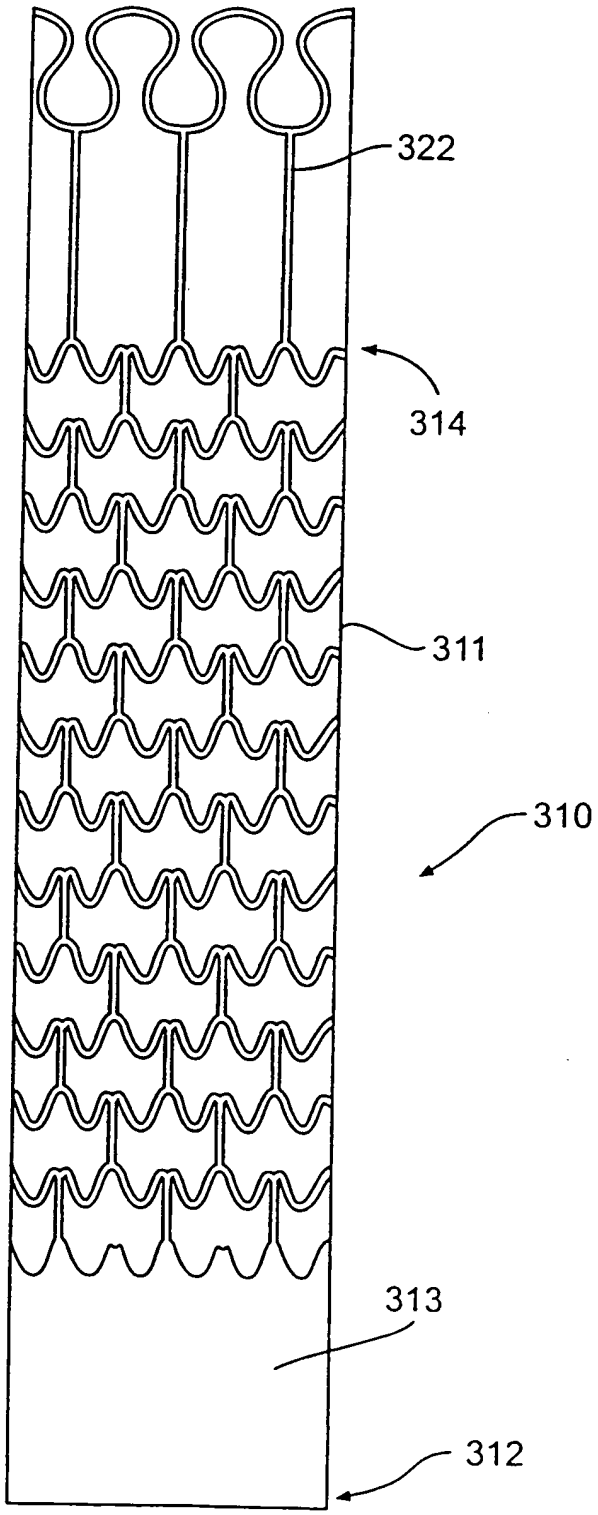


FIG. 34E

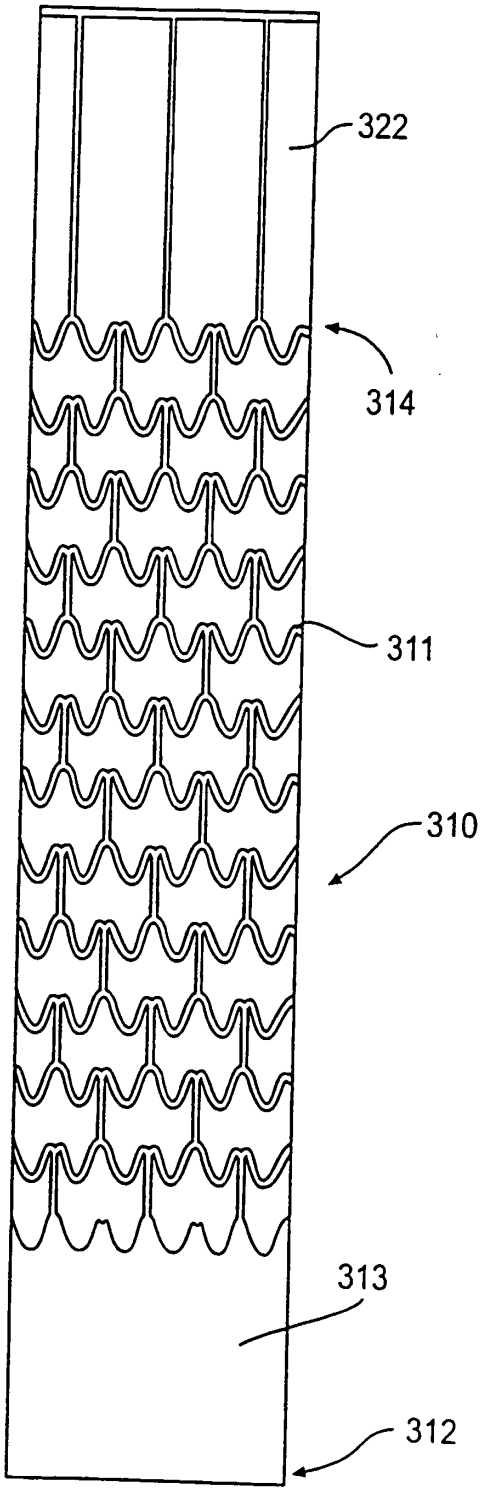


FIG. 34F

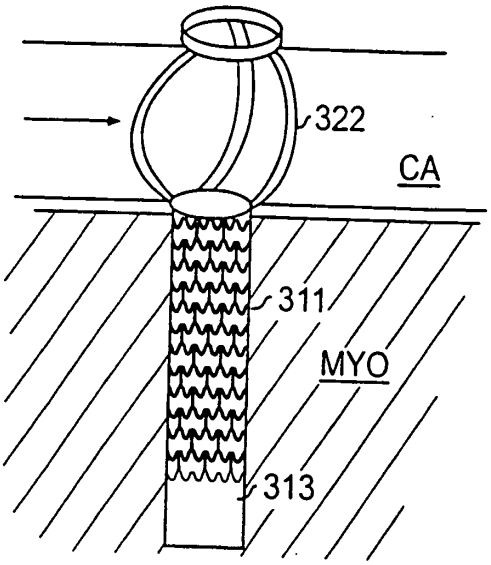


FIG. 34G

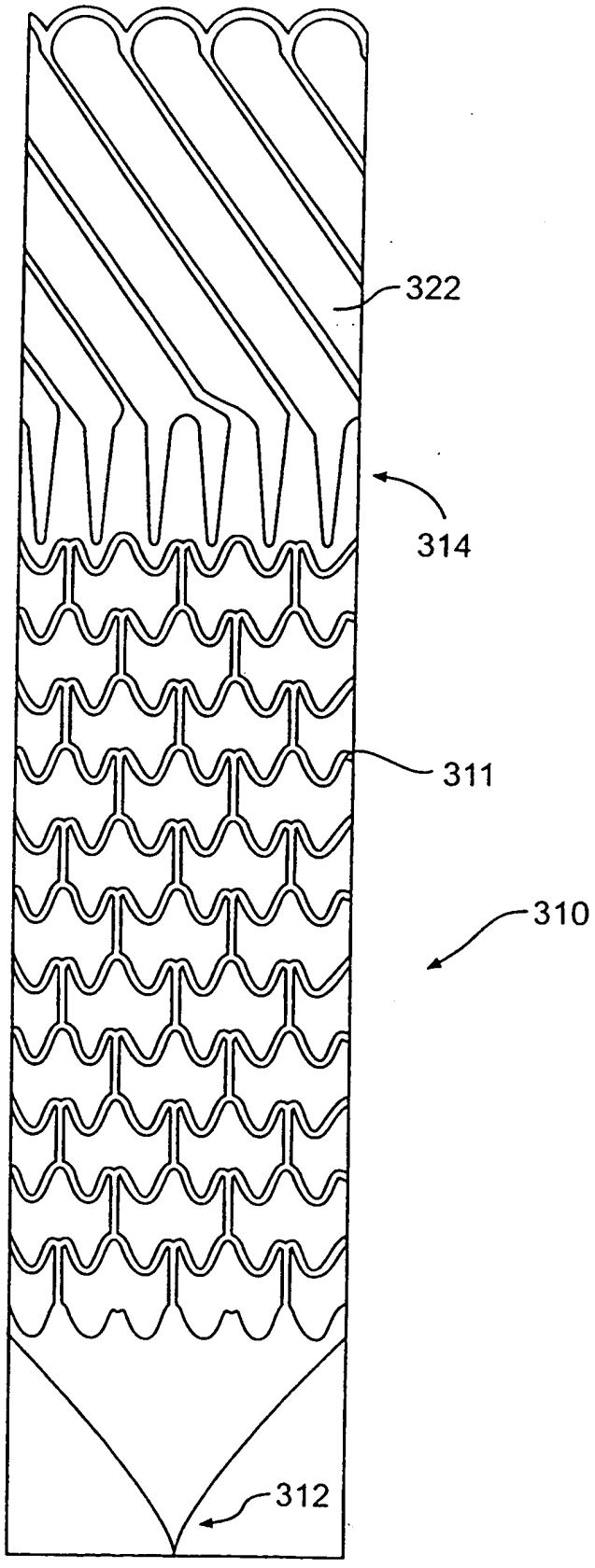


FIG. 34I

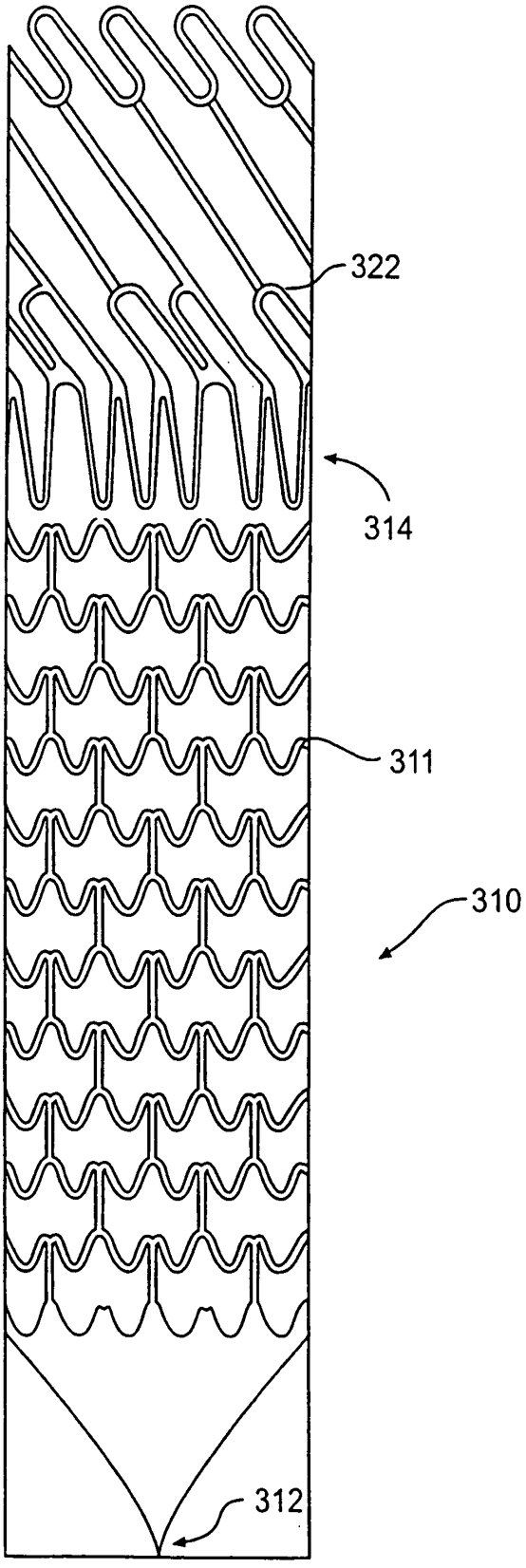


FIG. 34H

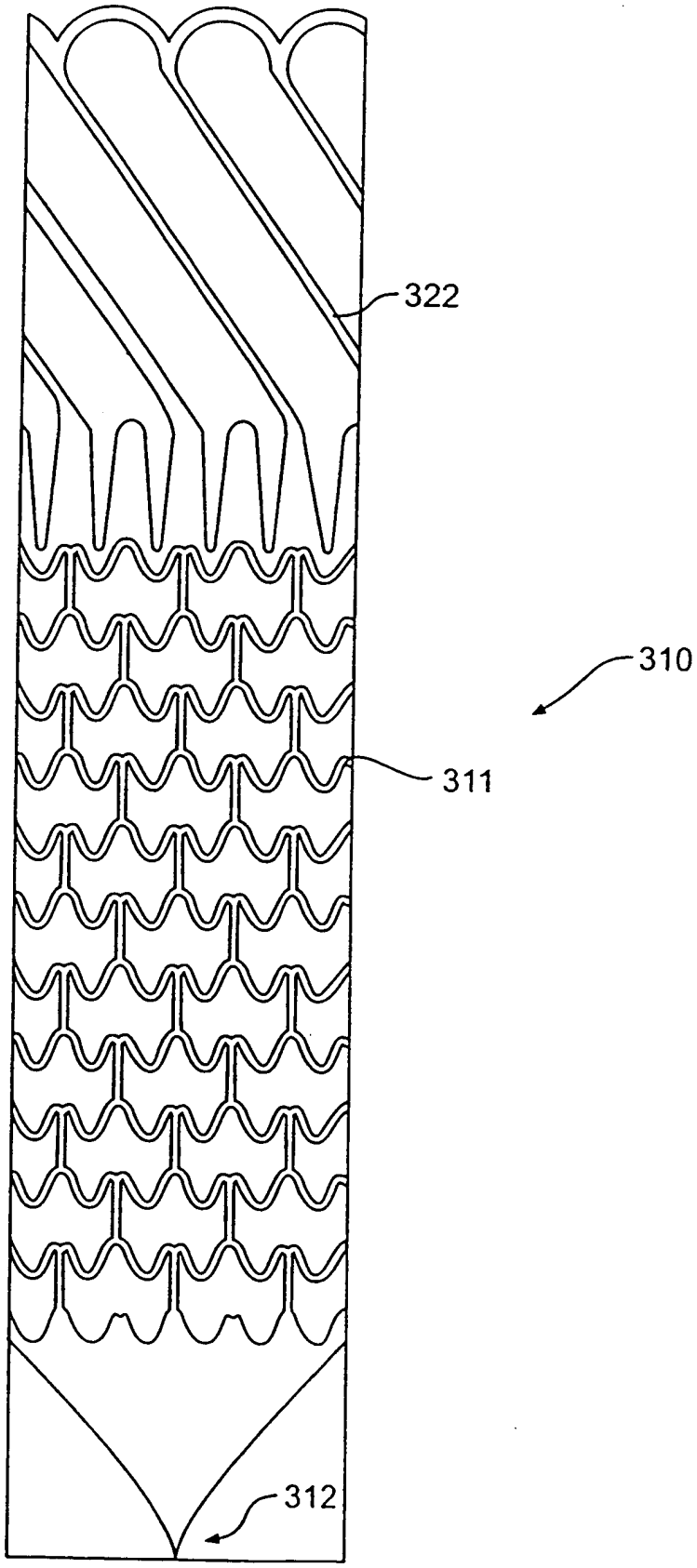


FIG. 34J

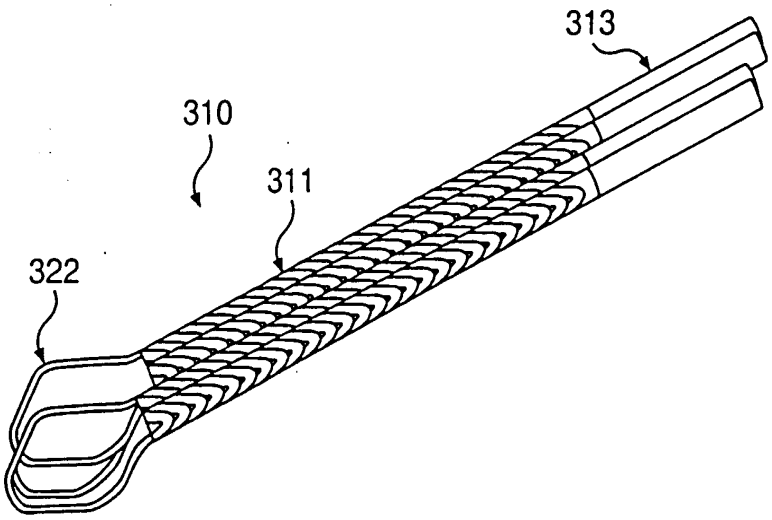


FIG. 34K

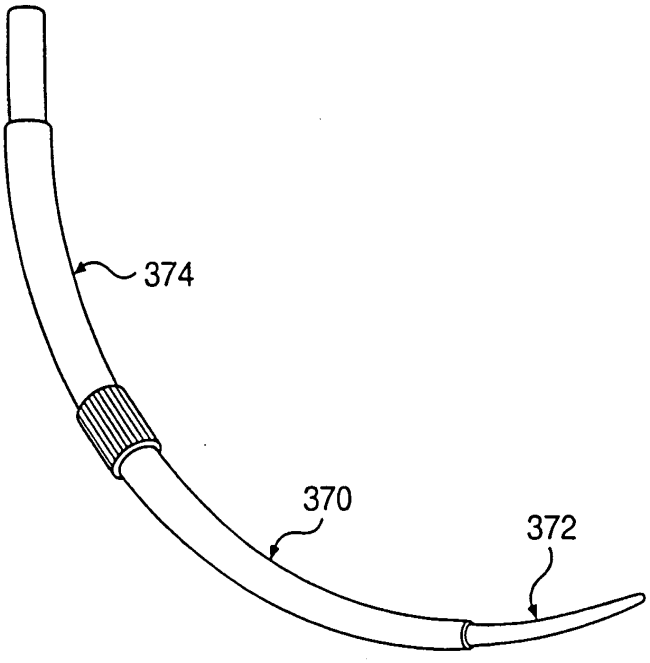


FIG. 34L

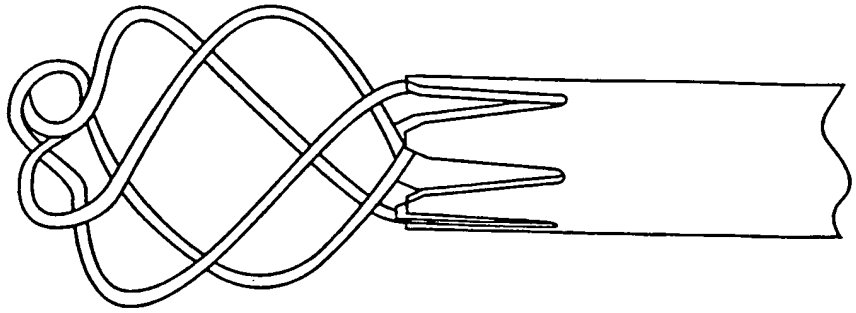


FIG. 35

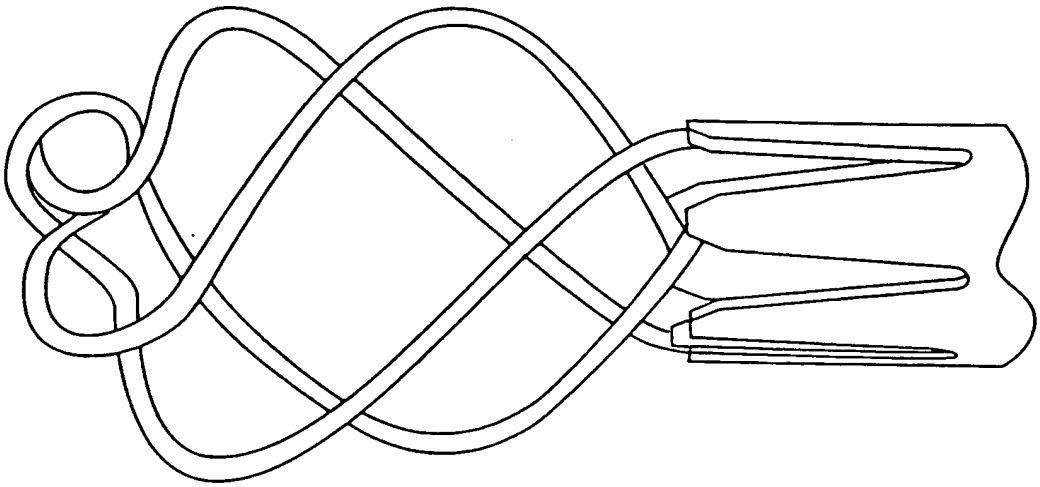


FIG. 36

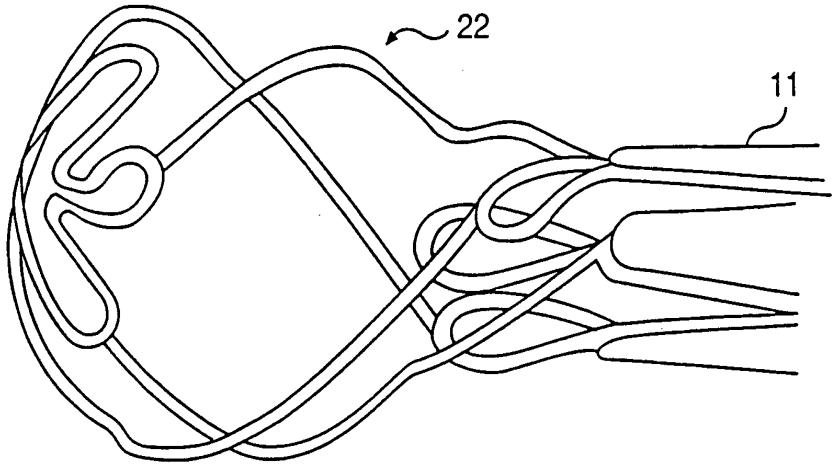


FIG. 37

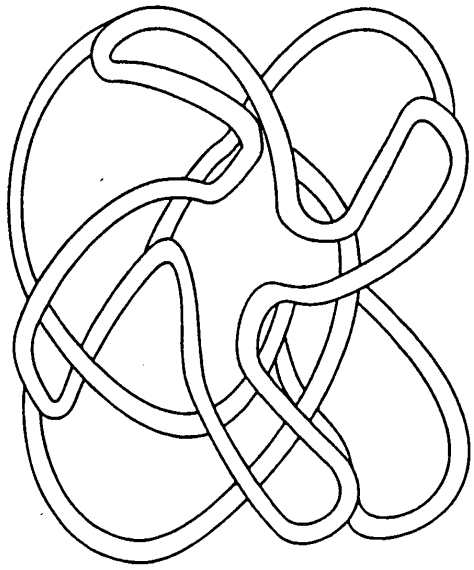


FIG. 38

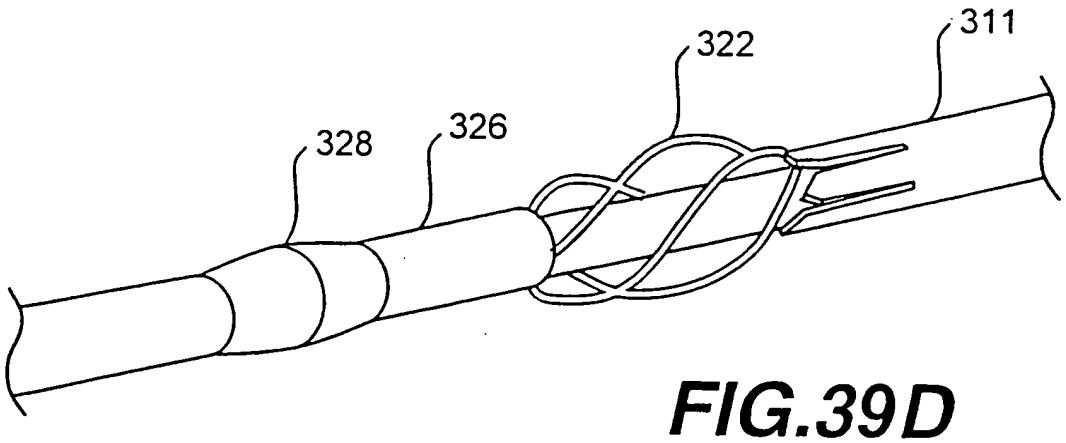


FIG.39D

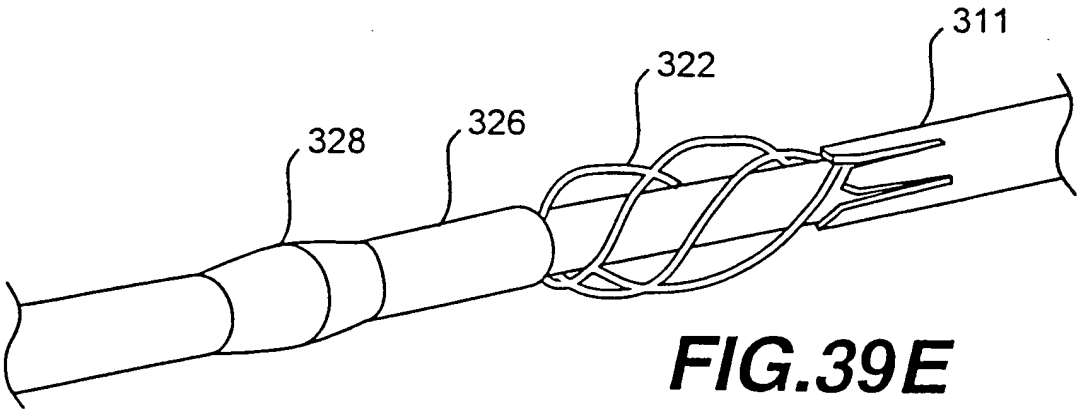


FIG.39E

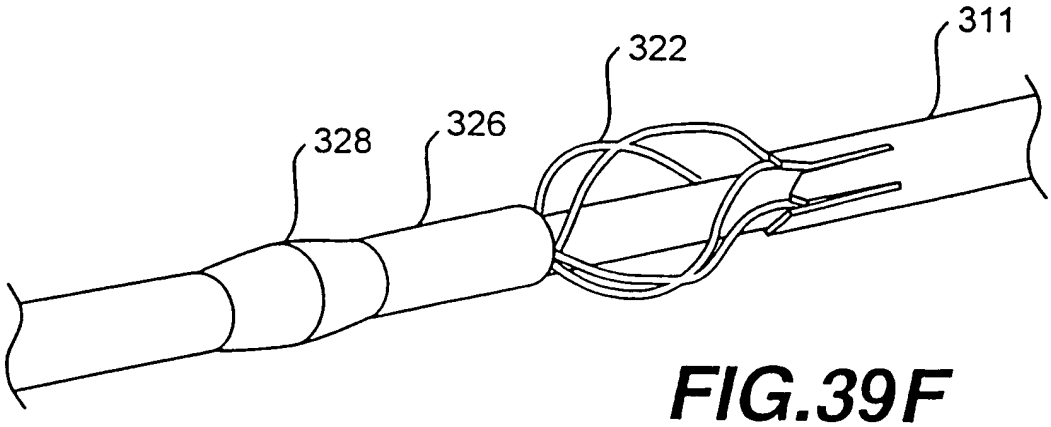


FIG.39F

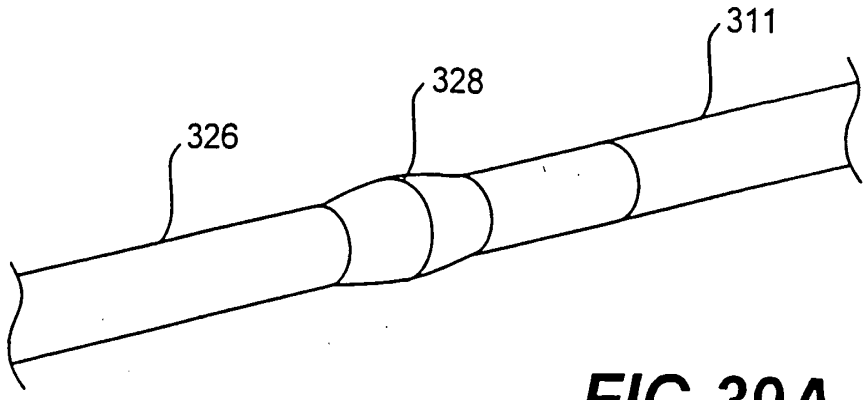


FIG.39A

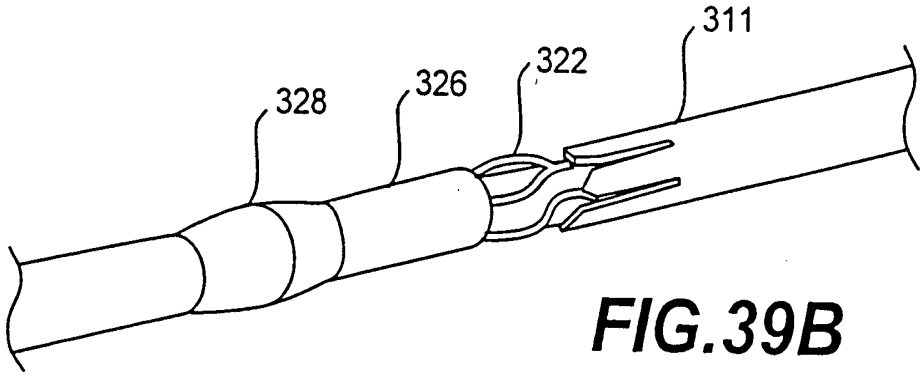


FIG.39B

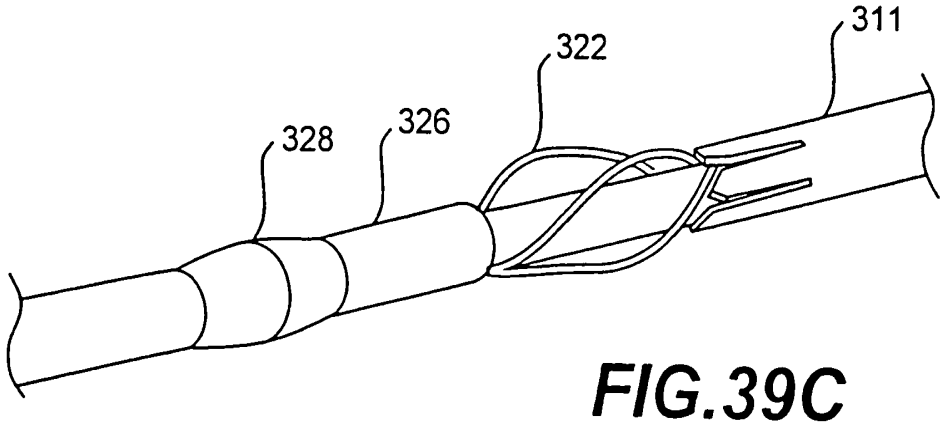


FIG.39C

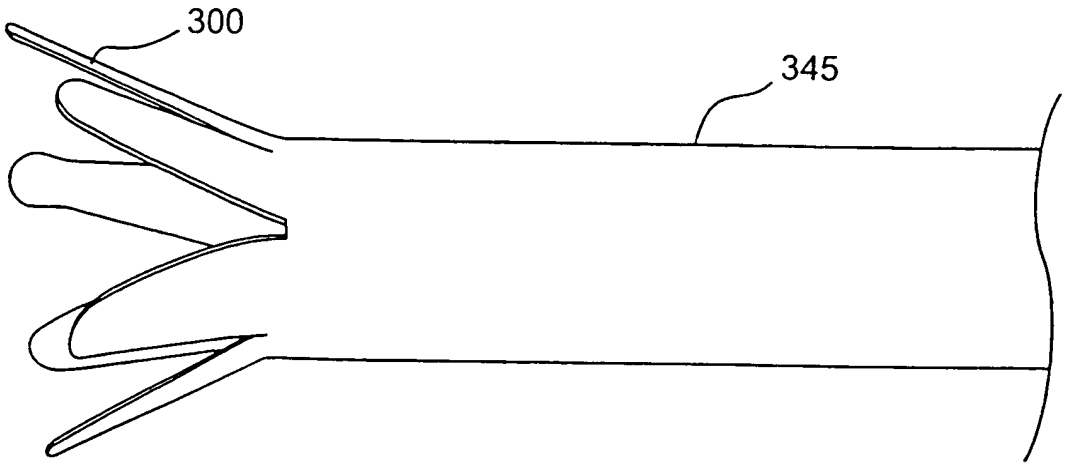


FIG. 40A

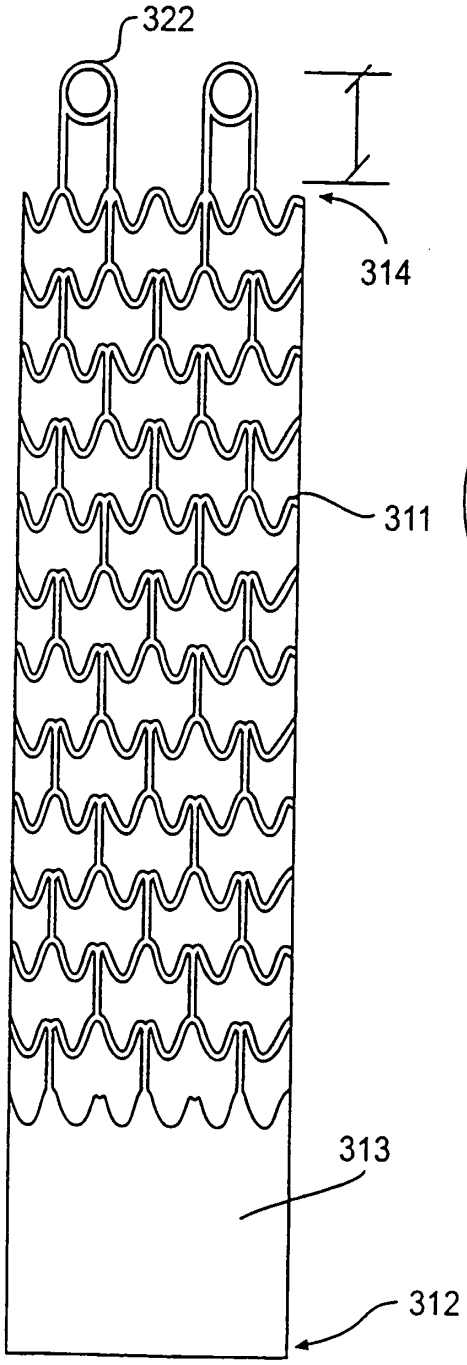


FIG. 40B

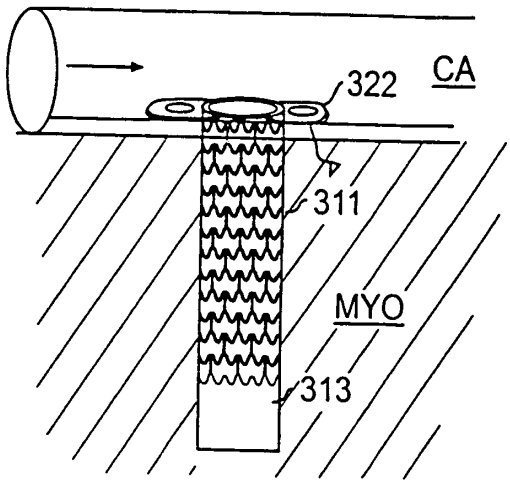


FIG. 40C

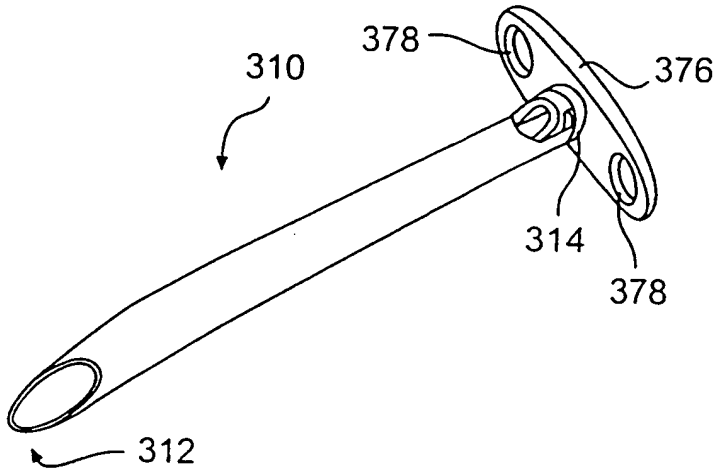


FIG. 41

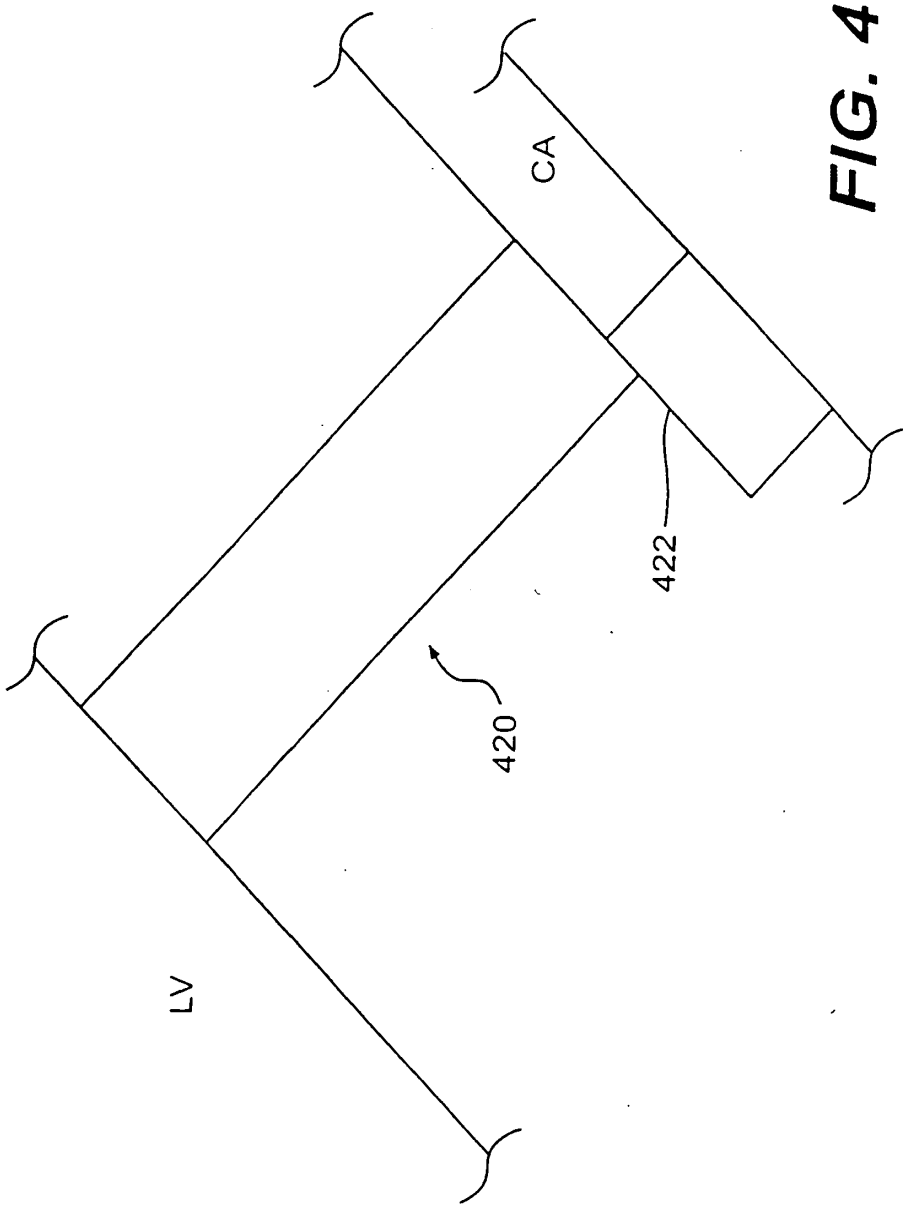


FIG. 42

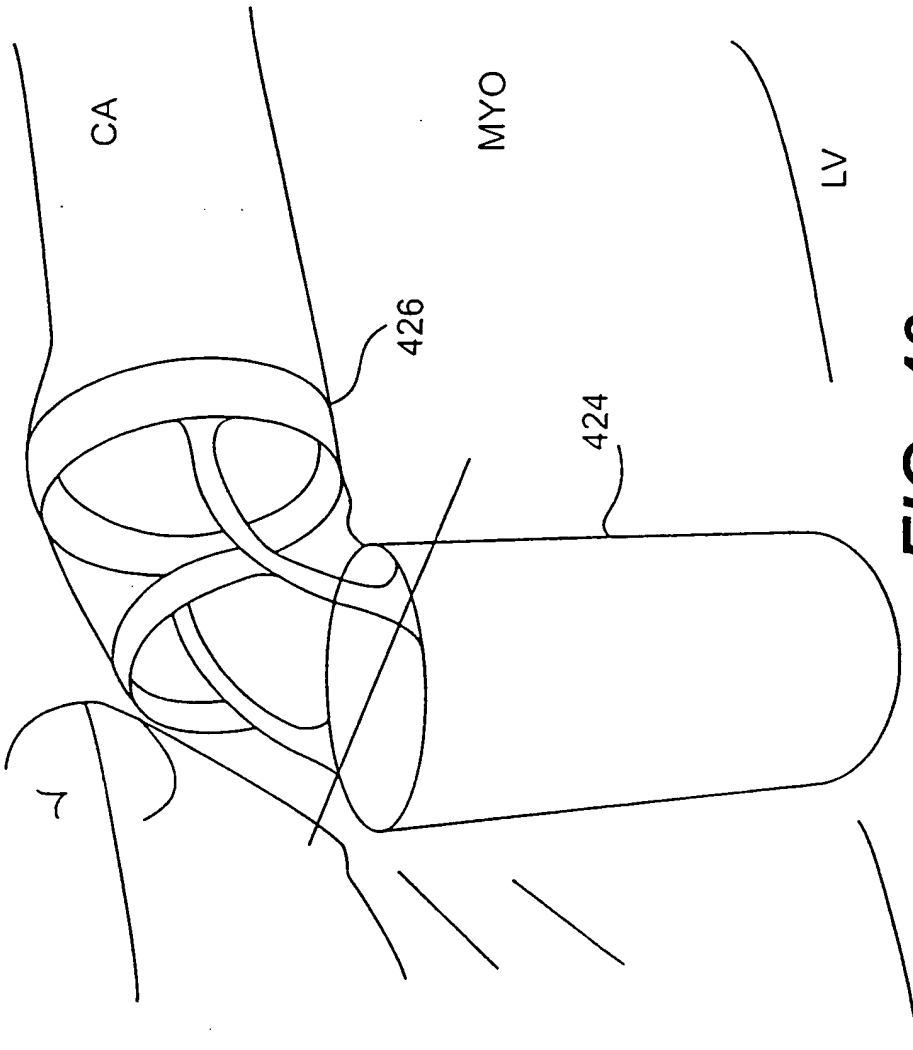


FIG. 43

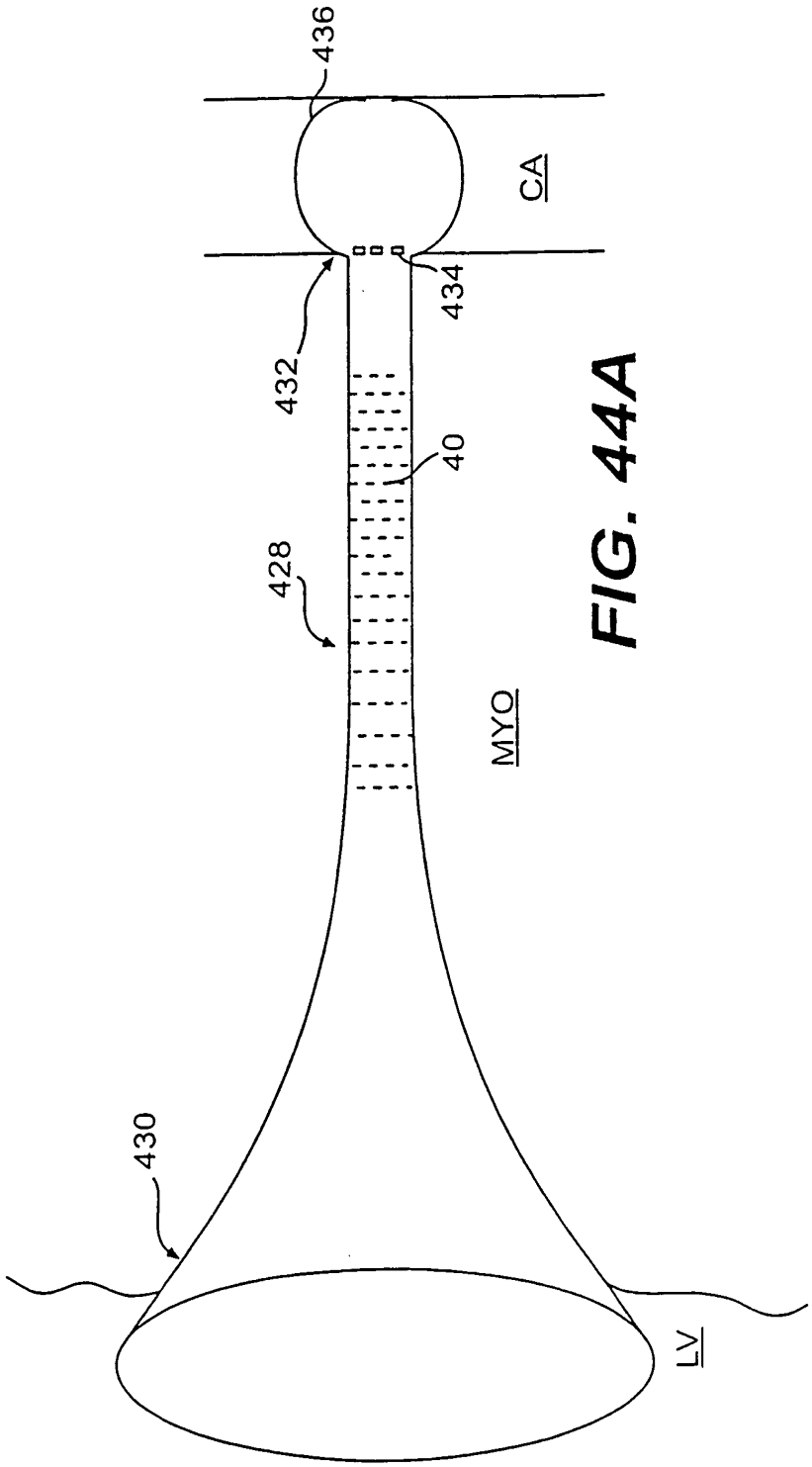


FIG. 44A

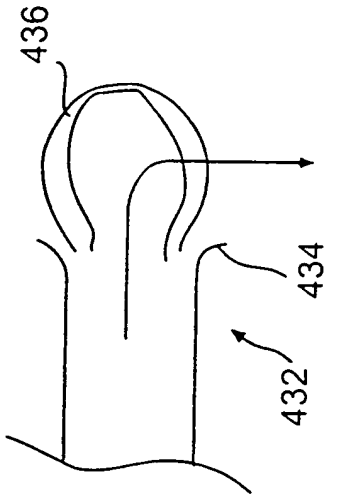


FIG. 44B

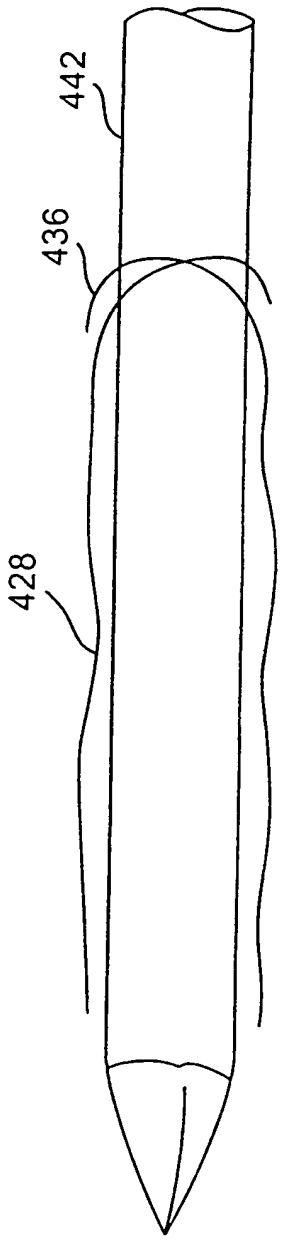


FIG. 44C

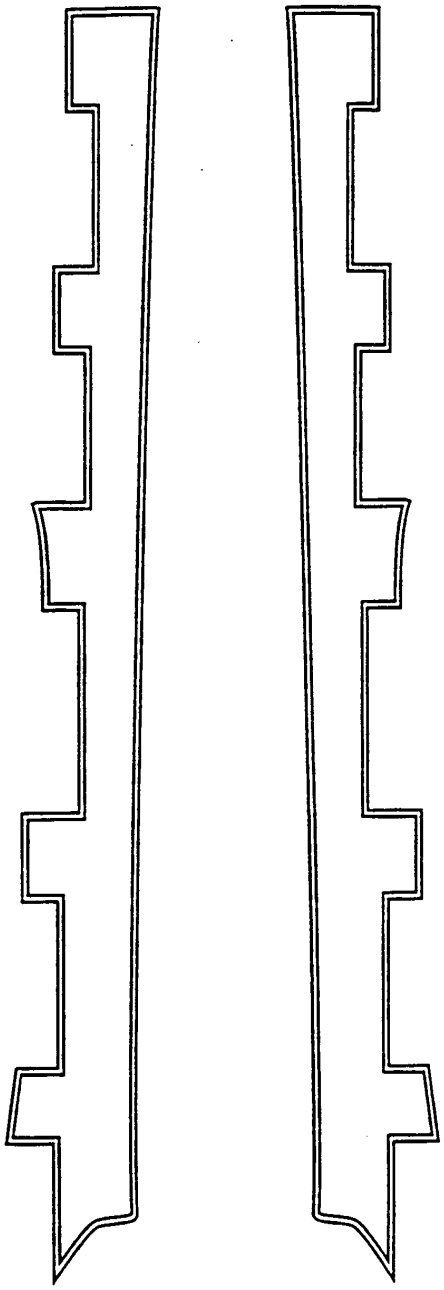


FIG. 46

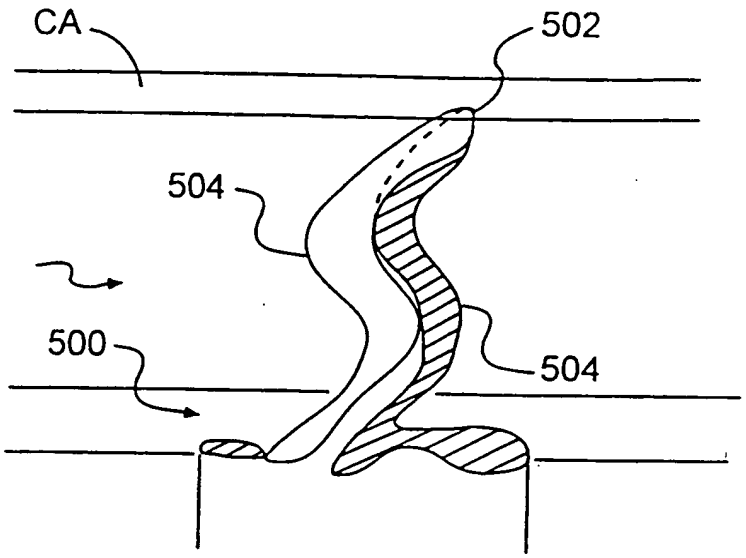


FIG. 47A

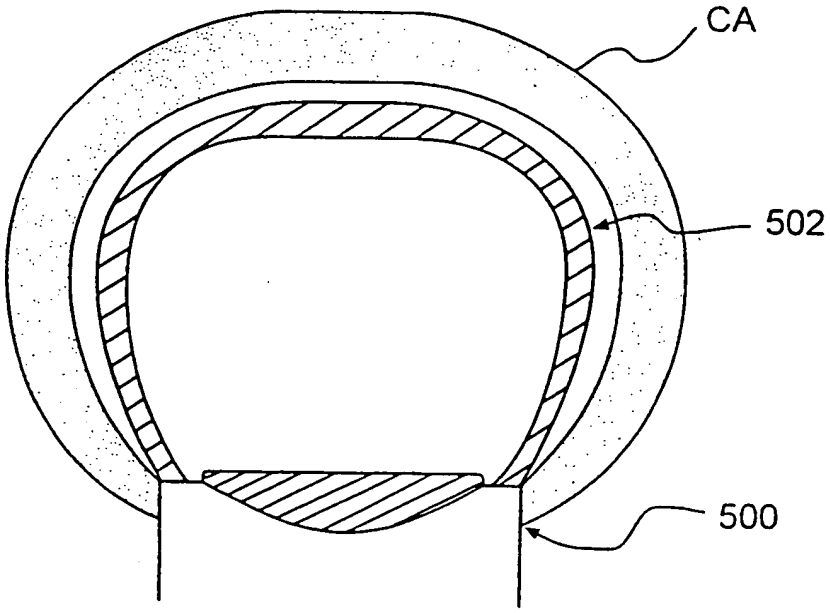


FIG. 47B

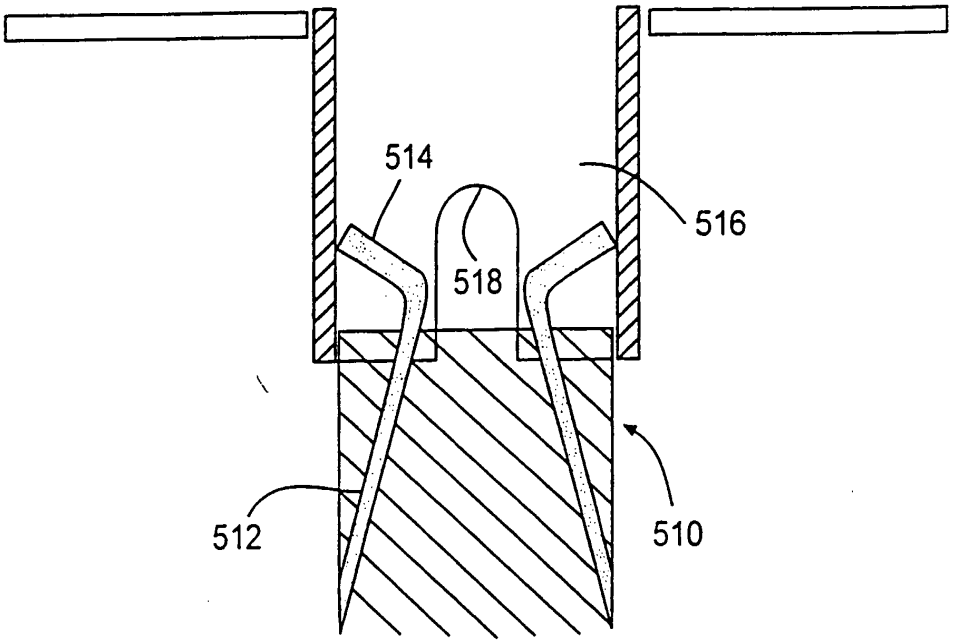


FIG. 48A

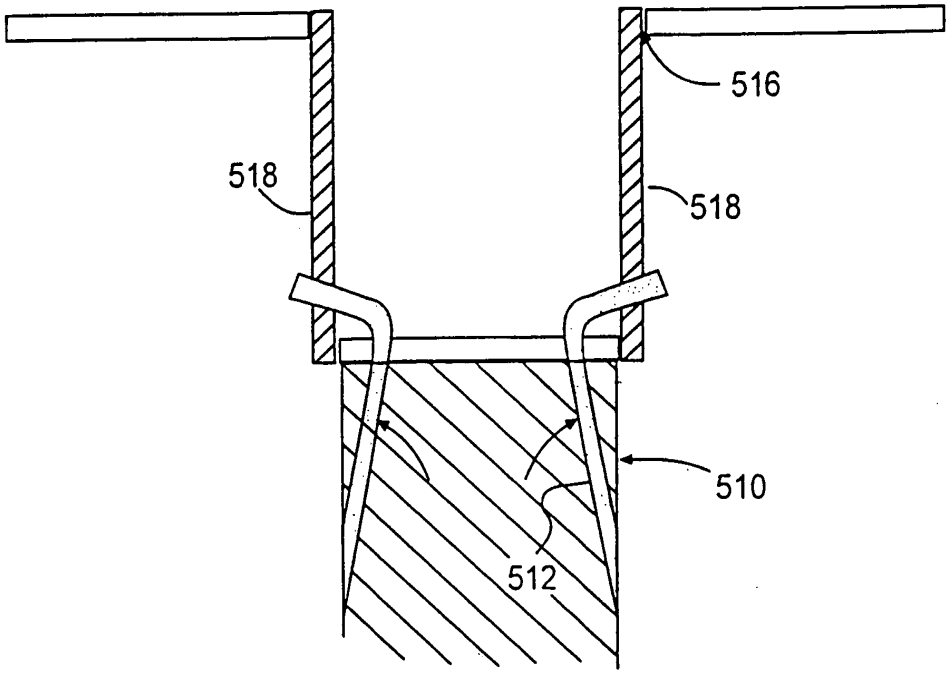


FIG. 48B

INTERNATIONAL SEARCH REPORT

Inter ial Application No
PCT/US 99/20714

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	WO 98 08456 A (TRANSVASCULAR INC) 5 March 1998 (1998-03-05) figures 1-8 page 12, line 26 -page 14, line 6 page 30, line 35 -page 33, line 13 ---	1-5, 11-13
X	US 5 429 144 A (WILK PETER J) 4 July 1995 (1995-07-04) figures 7-9 column 5, line 43 - line 65 column 8, line 1 - line 58 ---	1,3-5,11
X	US 5 655 548 A (SHMULEWITZ ASCHER ET AL) 12 August 1997 (1997-08-12) figures 4-6 column 6, line 7 -column 7, line 6 --- -/--	1,4,5,11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 2000	21/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter[illegible]al Application No
PCT/US 99/20714

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9808456	A	05-03-1998	AU	4234097 A	19-03-1998
US 5429144	A	04-07-1995	US	5409019 A	25-04-1995
			US	5287861 A	22-02-1995
US 5655548	A	12-08-1997	AU	4352497 A	02-04-1998
			WO	9810714 A	19-03-1998
			US	5824071 A	20-10-1998
US 5935119	A	10-08-1999	NONE		
WO 9936001	A	22-07-1999	AU	2324299 A	02-08-1999
WO 9732551	A	12-09-1997	US	5810836 A	22-09-1998
			EP	0891172 A	20-01-1998
			US	5971993 A	26-10-1999
			US	5878751 A	09-03-1999
WO 9921510	A	06-05-1999	US	5980548 A	09-11-1999
			AU	1079599 A	17-05-1999